UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HUMANA INC., Plaintiff, vs. REGENERON PHARMACEUTICALS, INC., Defendant.	**Case No. 21-cv-6245** **COMPLAINT** **DEMAND FOR JURY TRIAL**

Humana Inc. ("Humana") brings this Complaint against Regeneron Pharmaceuticals, Inc. ("Regeneron") and alleges as follows.

NATURE OF THE ACTION

1. This case arises out of a scheme between a drug manufacturer and a sham charity to defraud Medicare and its contracted payors out of hundreds of millions of dollars. For years, Defendant Regeneron has inflated the price of its age-related macular degeneration drug, Eylea, and then provided illegal kickbacks disguised as donations to the Chronic Disease Foundation ("CDF"), a purported "charity", to cover the cost-sharing obligations for patients who might have otherwise chosen cheaper alternatives to Eylea.

2. This scheme has contributed to Eylea's massive success; it generates billions of dollars in revenue annually for Regeneron and is the top-selling drug of its kind in the United States. But for this scheme, Eylea's inflated price—approximately $10,000 for just one year of treatment—would be cost-prohibitive for many patients, especially as compared to one of its competitors, Avastin, which is equally as effective but costs only 3% of the price of Eylea.

3. Regeneron operated its kickback scheme as follows: to prevent patients from seeking a more cost-effective drug alternative to Eylea, Regeneron began secretly and unlawfully funneling money disguised as donations to CDF, which CDF then used to pay for the cost sharing obligations (e.g., deductibles, co-payments, and co-insurance) of patients who were enrolled in Medicare plans (including Medicare Advantage and Medicare Part D plans) and who were in need of a drug like Eylea. While Regeneron's "donations" were ostensibly to assist with the cost-sharing obligations for any patient in need of a macular degeneration drug, Regeneron engineered the scheme so that its payments to CDF would only benefit patients receiving Eylea. Thus, patients could obtain Eylea at no cost to them instead of choosing drugs offered by Regeneron's competitors which were otherwise significantly cheaper. This operation eliminated any sensitivity by patients or their physicians to the true price of Eylea and at the same time, allowed Regeneron to price Eylea well-above what the market would otherwise support. In doing so, Regeneron relied on Medicare and other payors to pay for the remaining portion, i.e., the vast majority, of the drug's inflated price.

4. Regeneron's scheme was carefully and intentionally engineered to maximize its profits. In 2012, Regeneron determined that it could increase its prices dramatically if it paid patients' cost-sharing obligations by funneling the money through a third-party charity. Regeneron subsequently began coordinating with CDF to do just that. Regeneron sought, and CDF provided, information that allowed Regeneron to determine how much it needed to "donate" to CDF to cover and eliminate the cost-sharing obligations owed by Eylea patients who were insured by Medicare. Regeneron and CDF understood that there would be a corresponding one-to-one relationship between the amounts Regeneron paid in and the amounts that CDF paid out to fund Eylea patients' cost-sharing obligations. Pursuant to this understanding, and after

determining that such payments would generate a substantial return on investment, Regeneron funneled the carefully calculated payments through CDF.

5. For many years, Regeneron's scheme worked, and it generated massive profits from Eylea sales. Since 2013, Medicare programs have paid out approximately $11.5 billion to cover the cost of Eylea, and in 2019, Eylea sales generated $4.6 billion for Regeneron. Regeneron's profits have come at the expense of both the government and payors, including Humana, who bear the cost of spending for patients enrolled in Medicare plans. Humana, alone, has paid out more than $900 million to cover the cost of Eylea for patients enrolled in its Medicare Advantage and Medicare Prescription Drug plans.

6. While Regeneron managed to conceal its scheme for years, an investigation by the United States Department of Justice ("DOJ") recently unearthed the operation. On June 24, 2020, the DOJ filed a complaint against Regeneron, laying out Regeneron's violations of federal law, putting evidence of Regeneron's unlawful scheme into the public record, and explaining how Regeneron reaped billions of dollars at the expense of the federal government and payors like Humana.

7. As evidenced by the DOJ's complaint, Regeneron's scheme violated the False Claims Act, the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b), and various state laws that prohibit deceptive and unlawful conduct, including pharmaceutical companies paying their customers' cost-sharing obligations.

8. Regeneron's scheme has also harmed Humana in multiple ways. *First*, because the claims for Eylea submitted to Humana's Medicare plans were products of Regeneron's unlawful kickback scheme, they were not payable. Regeneron knew this, and therefore misrepresented and concealed the nature of its financial relationship with and use of CDF, to ensure that claims

continued to be paid. Specifically, Regeneron publicly stated that it did not play a role in funding CDF, and internal Regeneron emails uncovered by the DOJ show that Regeneron executives lied to company auditors who might have uncovered or outed Regeneron's unlawful conduct.

9. *Second*, Regeneron's conduct also interfered with, undermined, and defeated key provisions of Humana's Medicare plans with the individuals (called "members") enrolled in those plans. Under those plans, members are required to share in the cost of prescription drugs by paying copayments or coinsurance amounts related to those drugs. By paying kickbacks and funneling sums through CDF to eliminate Eylea patients' cost-sharing obligations, Regeneron tortiously interfered with Humana's plans with its members, and caused Humana to pay for Eylea when members had not met their required cost-sharing obligations.

10. In addition to harming insurers who offer and administer Medicare plans, Regeneron's conduct harmed the American public, by subjecting taxpayers and the programs that pay for taxpayers' healthcare costs to the inflated and excessive drug pricing of Eylea. Indeed, if patients used other drugs that were as effective as, but substantially cheaper than, Eylea, the federal government's Medicare program and taxpayers could save billions of dollars.

11. Accordingly, Humana brings this suit to recover damages and stop Regeneron's unlawful conduct.

PARTIES

12. Plaintiff Humana Inc. is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. Humana and its subsidiaries are providers of healthcare related services, including insuring risk for prescription drug costs for more than eight million members in all 50 states, the District of Columbia, and Puerto Rico. Among other things, Humana offers and administers Medicare Advantage health benefit plans and Medicare

Prescription Drug Plans. Humana is the second largest sponsor of these Medicare plans in the United States.

13. Defendant Regeneron Pharmaceuticals, Inc. is a New York corporation with its principal place of business in Terrytown, New York. Regeneron discovers, develops, and commercializes drugs, including the drug Eylea.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because it arises under the Constitution, laws, or treaties of the United States. Specifically, Humana asserts claims arising under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, *et seq*.

15. This Court also has subject matter jurisdiction over this action under 28 U.S.C. § 1332 because the matter is between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

16. This Court also has supplemental jurisdiction over Humana's state law claims, including state common-law claims, under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy.

17. This Court has personal jurisdiction over Regeneron because Regeneron is incorporated and headquartered in the State of New York.

18. Venue is proper in this district under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because Regeneron resides in this district and because a substantial part of the events giving rise to the claims in this action have occurred in this district. Specifically, Regeneron devised, directed, and carried out the unlawful scheme described in this Complaint in and from this district.

BACKGROUND ALLEGATIONS

Eylea and Other Drugs for Treating Macular Degeneration

19. Eylea, a drug manufactured and sold by Regeneron, is used to treat a type of eye disease called neovascular or "wet" age-related macular degeneration ("AMD").

20. There are two types of AMD: nonexudative or "dry" AMD and neovascular or "wet" AMD. Dry AMD accounts for 90 percent of cases in the United States and progresses slowly, with minimal early-stage symptoms. Wet AMD, though less common, is associated with more severe symptoms, where blood vessels in the back of the eye can grow in abnormal ways, bleed, and leak, which can cause blind spots and other vision problems. Wet AMD can also follow dry AMD. People who suffer from wet AMD can become legally blind.

21. Sometimes, wet AMD is treated with photodynamic therapy, in which lasers and light-sensitive medicine are used in combination to break down blood vessels that have experienced abnormal growth. But more commonly, wet AMD is treated with "anti-VEGF" drugs administered via injection, which reduce swelling and impede the growth of blood vessels that cause wet AMD. Anti-VEGF injections slow, but do not prevent, vision loss, and therefore need to be administered to patients who suffer from wet AMD regularly and indefinitely.

22. Regeneron obtained FDA approval for Eylea in 2011, and has subsequently turned Eylea into its most profitable drug, generating billions of dollars in sales every year.

23. Although Eylea is extremely lucrative for Regeneron, it is neither the most effective nor the least expensive anti-VEGF drug at $1,850 per dose. It is recommended that patients on Eylea receive an injection once every four weeks for the first five doses, then once every eight weeks after that, bringing the cost of Eylea injections to over $10,000 *per year*.

24. A different company, Genentech, Inc., manufactures and sells two drugs that compete with Eylea. One of those drugs, Lucentis, is an anti-VEGF drug approved by the FDA to treat

wet AMD and priced at $2,000 per dose. The other drug, Avastin, is chemically similar to Lucentis but is approved by the FDA only to treat certain forms of cancer. However, clinical studies have shown that Avastin is comparably effective to Eylea and Lucentis in treating wet AMD if used off-label to do so.[1] Avastin provides the same benefits as both Eylea and Lucentis, but costs far less; indeed, compounding pharmacies sell Avastin for just $55 per dose (approximately 3% of the cost of Eylea) to treat wet AMD via off label use.

25. Doctors generally prescribe Avastin instead of Eylea (or Lucentis) when financial considerations come into play. Tellingly, Richard O'Neal—Vice President of Market Access at Regeneron—recently testified that federal regulations lowering the Medicare reimbursement rate for Eylea created a "looming need [for doctors] to switch patients from EYLEA to off-label Avastin," and "at least some patients who were switched from EYLEA to off-label Avastin (or other drugs) would be unlikely to return to EYLEA."[2]

26. Despite Avastin being cheaper than Eylea and equally as effective, Eylea remains the top-selling drug for treating wet AMD in the United States.

27. In 2019, Medicare Part B (explained below) spent more on Eylea than any other drug. The Centers for Medicare and Medicaid Services ("CMS") recently cited Eylea as an example of

[1] National Eye Institute, *Avastin as Effective as Eylea for Treating Central Retinal Vein Occlusion* (May 9, 2017), https://www.nei.nih.gov/about/news-and-events/news/avastin-effective-eylea-treating-central-retinal-vein-occlusion.
[2] *See* Declaration of Richard O'Neal in Support of Plaintiff's Order to Show Cause for Preliminary Injunction, Temporary Restraining Order, and Expedited Briefing Schedule (Dkt. 13), *Regeneron Pharmaceuticals, Inc. v. U.S. Department of Health and Humans Services*, Case No. 7:20-cv-10488 (S.D.N.Y. Dec. 11, 2020).

the need for drug-pricing reform in the United States, noting that Eylea is "approximately two times as expensive in Medicare Part B as in comparison countries."[3]

Design of Health Benefit Plans and the Impact of Eliminating Cost-Sharing Obligations

28. When a person purchases or signs up for a type of insurance, they enroll in a health benefit plan. The plan sets forth terms and conditions identifying whether things like drugs, healthcare services, and other items will or will not be paid for by the administrator, and in what amount.

29. In the United States, benefit plans are designed and structured to play an essential role in managing healthcare costs. This is particularly true with respect to spending on drugs, because there are no limits or caps on drug prices.

30. Specifically, benefit plans are designed and structured to sensitize plan beneficiaries to the cost of the drugs or care they receive. The plans do this by requiring beneficiaries to "share" in the cost by paying for a portion of the drugs or services they receive. The amounts beneficiaries are required to pay are called "cost-sharing obligations," and can take the form of deductibles (amounts the beneficiary must pay before the health plan pays), coinsurance amounts (amounts that constitute a percentage of the cost of the item or service received), and copays (fixed amounts). By requiring beneficiaries to pay cost-sharing obligations, benefit plans sensitize them to the cost of their care, incentivize them to consume less expensive drugs and services, and can shift their behavior toward using lower cost alternatives when they are available. When lower cost alternatives are not available, cost-sharing obligations still sensitize

[3] Centers for Medicare & Medicaid Services, *FACT SHEET: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period* (Nov. 20, 2020), *available at* https://tinyurl.com/lj8hbs85.

beneficiaries to the cost of drugs and services, which puts downward pressure on how high those drugs and services can be priced, especially the most expensive drugs and services.

31. Because cost-sharing obligations require patients to pay for a portion of their care, they also sensitize the patients' physicians to the cost of that care. Simply put, physicians know that the price of the services they order and the drugs the prescribe can have significant financial impacts on their patients because of cost-sharing obligations built into benefit plan design, and therefore are incentivized to order and prescribe lower cost items when possible.

32. Many for-profit healthcare providers and drug companies, like Regeneron, strongly dislike cost-sharing obligations, because they function as a barrier to charging, and getting paid, maximum amounts on drugs—like Eylea—without losing customers. In other words, by sensitizing patients and their physicians to the cost of Regeneron's drugs, cost-sharing obligations limit Regeneron's ability to charge inflated prices without suffering adverse consequences in terms of patient usage and profit.

33. Motivated by greed, and unwilling to lower the prices they charge for their drugs, many drug manufacturers have attempted to find ways to eliminate the cost-sharing obligations that benefit plans impose on beneficiaries. One way they do this is by paying the obligations themselves, having calculated that, by paying the cost-sharing obligations, they can keep patients on their drugs and recoup massive returns on their investment in the form of payments from insurers for the remaining portion of the astronomical price of the drugs. The result of the drug manufacturers' payments, which are effectively routine cost-sharing waivers, is that neither patients nor their physicians are sensitized to the cost of the drugs, allowing the drug manufacturers to attract customers, keep their customers, and maintain or inflate the prices they charge, without worrying about any adverse impact of those actions on their profits.

34. The effect of cost-sharing waivers on drug prices is well studied. For example, a large study conducted in Germany in 1989 showed that when drug companies were prevented from waiving cost-sharing obligations, drug prices dropped between 10 and 26 percent on average. In other words, the companies were able to substantially inflate their prices simply by waiving patients' responsibility to share in the cost of the drugs.

35. Researchers have also discussed the effect of patient assistance programs sponsored by drug companies on drug spending and cost. For example, in a 2009 article, researchers noted:

> Drug company–sponsored PAPs [Patient Assistance Programs] may inhibit cost-effective medication use, and their widespread use may have important implications for public drug spending. This potential impact must be better understood. Drug company–sponsored PAPs may steer patients toward and lock them into a particular manufacturer's product, even when other equally effective and less costly alternatives are available. If these patients ultimately acquire better coverage, then they may request unnecessarily expensive medications. In the case of Medicare Part D, patients' prior use of PAPs that provide subsidies for brand-name products may lead to higher overall individual and public drug spending.[4]

36. Similarly, researchers in a 2014 article explained:

> Assistance programs are a triple boon for manufacturers. They increase demand, allow companies to charge higher prices, and provide public-relations benefits. Assistance programs are an especially attractive proposition for firms that sell particularly costly drugs. Faced with high out-of-pocket costs, some patients may decide against taking an expensive medication. Patient-assistance programs can convert such patients from nonusers to users. Programs must incur costs for patients who would have used the drug even in the absence of a program, but manufacturers can afford to pay a lot of $25 or $50 copayments in return for even a small increase in the sales of a $50,000 drug.[5]

37. In sum, by paying patient cost-share obligations, drug manufacturers like Regeneron can remove mechanisms that put downward pressure on their prices and act as barriers to

[4] Choudhry, Niteesh K *et al*., *Drug company-sponsored patient assistance programs: a viable safety net?,* Health Affairs (Project Hope), Vol. 28, No. 3 (2009), https://tinyurl.com/y33pp57k.
[5] David H. Howard, *Drug Companies' Patient-Assistance Programs—Helping Patients or Profits?*, New England Journal of Medicine (2014), https://tinyurl.com/y66kwwea.

unrestrained, inelastic consumption. Healthcare payors, whether it be the federal government or plan sponsors such as Humana, must then pay for the bulk of the inflated prices charged by the manufacturers, providing the funds that manufacturers pocket as windfall profits.

38. In this case, Regeneron designed and carried out its conduct for the specific purpose of undermining, eliminating, and defeating the cost-sharing obligations that Humana and other insurers' benefit plans required patients to satisfy, which stood as barriers to Regeneron charging and getting paid as much as possible for Eylea.

39. Specifically, Regeneron used CDF as a financial conduit through which to funnel funds calculated to specifically pay for the cost-sharing obligations of Eylea patients, thereby eliminating and waiving the obligations, and desensitizing Eylea patients and their prescribing physicians to the inflated cost Regeneron charged for the drug.

40. This tortious conduct is responsible for Eylea's financial success. Indeed, because Regeneron managed to covertly fund and eliminate the portion of the cost of Eylea usually borne by patients, it effectively rendered Eylea "cheaper" or even free to patients, including with respect to a competing drug that is far less expensive. In doing so, Regeneron subverted and interfered with the design of the health benefit plans like those offered by Humana, which are intended to encourage patients and their physicians to select cost-effective care.

Humana's Medicare Advantage Plans

41. The national health insurance program in the United States known as Medicare has four parts – A, B, C, and D – through which health benefits are provided to individuals who qualify for them.

42. Part A covers inpatient hospital services, skilled nursing facility services, and some forms of home-based care. Part B covers physician services, outpatient hospital services, diagnostic services, and other medical services. Parts A and B also cover drugs delivered during

medical procedures, and Part B specifically pays for drugs provided incident to treatment at a physician's office (called "clinically administered drugs"), so long as the drugs are used consistent with FDA approval or in another medically accepted manner. The federal government directly administers Parts A and B through CMS.

43. Individuals who are eligible for Part A and enrolled in Part B have the option of enrolling in Medicare Part C, otherwise known as Medicare Advantage, which is required to offer the same benefits covered by Parts A and B, and also typically covers outpatient prescription drugs. CMS offers Medicare Advantage plans through private payors like Humana. Known as Medicare Advantage Organizations ("MAOs"), these payors provide Medicare Advantage plans to individuals pursuant to contracts with CMS.

44. Medicare Advantage plans are underwritten with taxpayer funds. For instance, CMS pays Humana a fixed amount each month for each person enrolled in Humana's Medicare Advantage plans. Humana manages the funds it receives from CMS to ensure that the benefits offered by Humana's Medicare Advantage plans are available to the members enrolled in those plans when they need them.

45. Humana offers and administers Medicare Advantage plans that provide the types of benefits discussed above, including coverage of Eylea, as it is a clinically-administered drug.

46. In offering and administering these plans, Humana bears significant risks related to the cost and utilization of healthcare services and pharmaceuticals. When Humana assumes these risks, it relies in large part on the protections afforded by state and federal law prohibiting unlawful conduct within the healthcare industry, including law prohibiting the submission of false, fraudulent, or otherwise unlawful claims to government and other payors.

47. Healthcare claims are not payable under Medicare if they do not comply with all applicable federal laws, including laws like the Anti-Kickback Statute, as discussed below.

48. Indeed, as a condition of participating in Medicare, providers must certify that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act))."[6] Providers also submit claims for Medicare beneficiaries to the government and to payors like Humana using a standard claim form, the CMS 1500, which requires the provider to certify that each claim "complies with all Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute."

49. Humana's Medicare Advantage plans, like most Medicare Advantage plans, also contain requirements that are designed to control the cost of healthcare. Specifically, Humana's Medicare Advantage plans contain provisions requiring enrolled members to pay their cost-sharing obligations. Cost-sharing obligations can be in the form of required deductibles (amounts members must pay before the plan pays), coinsurance (amounts members must pay as a percentage of the charge for what they receive), or copays (fixed amounts).

50. The details of the Medicare Advantage plans Humana offers and administers are set forth in plan policy documents, including in a type of document called an "Evidence of Coverage" ("EOC"). EOCs describe the health care benefits a plan offers, including what a plan covers and how much enrolled members pay for services. CMS requires that payors use certain

[6] CMS Form 855I

approved, publicly available language in their plan policy documents, and Humana uses that language for its own Medicare Advantage EOCs.

51. For example, the Humana Gold Plus plan, a Medicare Advantage plan that served select counties in Florida, is an EOC written for the year 2016 and incorporates Medicare's model language is attached as Exhibit 1.

52. Pursuant to the Humana Gold Plus plan, enrolled members paid 20% coinsurance for Medicare Part B Covered Drugs such as Eylea. *Id.* at 64.

53. Members were required to pay coinsurance until they hit their annual out-of-pocket maximum of $6,700. *Id.* at 51. Once these thresholds were met, members received 100% coverage for the rest of the plan year. *Id.*

54. The Humana Gold Plus plan members are themselves responsible for paying their cost sharing. *See e.g., id.* at 157. Cost sharing is defined as the "amounts that a ***member*** has to pay when services or drugs are received." *Id.* at 206 (emphasis added). The Plan defines member as "[a] person with Medicare . . . who has enrolled in [Humana's] plan and whose enrollment has been confirmed" by CMS. *Id.* at 211. Put simply, the Plan does not contemplate pharmaceutical manufacturers paying members' cost-share obligations.

55. Humana's other Medicare Advantage Plans contain materially similar provisions.

Humana's Medicare Part D Prescription Drug Plans

56. Humana administers Medicare Part D Prescription Drug Plans for Medicare beneficiaries. Humana also administers Medicare Advantage plans that combine with Prescription Drug Plan Benefits to create a comprehensive benefit. While Eylea is predominantly reimbursed through Medicare Advantage, at times it may be reimbursed through a pharmacy under a Part D plan.

57. Medicare Part D is an optional Prescription Drug Benefit plan ("PDP"); i.e., it is health plan that covers part of the costs of prescription drugs purchased by patients from pharmacies. Medicare Part D PDPs are administered only by private payors like Humana—CMS does not directly administer any PDPs. Medicare Part D enrollees must pay the private administrator of their prescription benefit plan a premium for their prescription drug benefit. CMS then pays a subsidy to the private administrator of the PDP plan based on each enrollees' health risk score, as determined by CMS.

58. There are several stages of reimbursement under Medicare Part D, but beneficiaries are required to pay some cost-sharing obligations at each of them. *See, e.g.*, Ex. 1 at 112.

59. The Humana Gold Choice plan explicitly states that "[i]t matters who pays." Only when a member pays for their cost sharing themselves do those payments count towards their out-of-pocket costs. *Id.* at 121.

60. Further, the Plan considers patient assistance programs to be outside the plan benefits, thus Humana will not pay "for any share of [those] drug costs." *Id.*at 133. In effect, by opting for patient assistance for their drugs, members are utilizing a different insurance than Humana.

61. Humana's other Medicare prescription drug plans contain materially similar provisions.

62. In this case, the cost-sharing payments made by CDF would not count toward a beneficiary's out-of-pocket costs because those payments were actually made by Regeneron and were not truly charitable, consistent with the allegations set forth in this complaint.

63. As with commercial insurance, cost-sharing requirements for Federal health care programs serve an important role in protecting both the Federal health care programs and their beneficiaries. Specifically cost-sharing requirements promote: (1) prudent prescribing and

purchasing choices by physicians and patients based on the true costs of drugs; and (2) price competition in the pharmaceutical market.

Legal Prohibitions on Drug Companies Paying Patient Cost-Sharing Obligations

64. Federal laws, including the AKS, prohibit drug companies from paying the cost-sharing obligations of the patients who use and are prescribed their drugs. The AKS makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal healthcare program.

65. Because Medicare Advantage is a "Federal health care program" as defined by 42 U.S.C. § 1320-7b(f), pharmaceutical companies like Regeneron who obtain reimbursement for their drugs through any Medicare Advantage plan must comply with the AKS.

66. A drug company's payment, or waiver, of patients' cost-sharing obligations, including by using "charities" as conduits through which to do so, violates the AKS when the patient is enrolled in a Medicare Part A, B, C, or D plan.

67. The federal government, through the Office of Inspector General ("OIG"), has issued guidance documents called "Bulletins" explaining this further. For example, in 2005 the OIG issued a Bulletin (*see* 70 Fed. Reg. 70623 (Nov. 22, 2005)) regarding "patient access programs" ("PAPS"). The OIG explained that PAPS that were funded by drug manufacturers and used to subsidize Medicare Part D cost-sharing obligations presented heightened risk under the AKS. The OIG stated that in some circumstances, and only if certain safeguards were met, cost-sharing subsidies that were provided by organizations that were real, independent charities that were not also affiliated with drug manufacturers could be appropriate.

68. But the OIG also stated that "[f]or purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded, or controlled by a manufacturer or any of its affiliates, to be a *bona fide*, independent charity, because interposition

of the entity would not sever the nexus between patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer . . .and would provide subsidies only for the manufacturer's products."[7] The OIG further stated that "where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs." And the OIG expressed a concern that the use of cost-sharing subsidies to shield plan beneficiaries from the economic effects of drug pricing would eliminate a market safeguard against inflated prices.

69. The OIG stated a PAP could be compliant with federal law only if all of the following were true:

a. The third-party administering the program is an independent, *bona fide*, charity;
b. Neither the manufacturer or any affiliate exert any direct or indirect influence or control over the charity or program;
c. Assistance is awarded in a truly independent manner that severs any link between the manufacturer's funding and the beneficiary;

[7] 70 Fed. Reg. 70623 (Nov. 22, 2005))

d. The charity awards assistance without regard to the beneficiary's choice of product, provider, practitioner or supplier;

e. Assistance is based on a reasonable, verifiable, and uniform measure of financial need applied in a consistent manner;

f. The manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products; and

g. The manufacturer does not earmark its donations for narrow disease categories (or for use of a specific drug) which, for example, were defined by reference to specific symptoms, severity of symptoms, or method of administration of drugs.

70. In 2014, OIG issued a Supplemental Bulletin relating to "indirect remuneration" that drug companies were providing "to patients" through "contributions to PAP[s]" operated by independent charities (*see* 79 Fed. Reg. 31120-31123 (May 30, 2014)). The OIG repeated that "[i]f a donation is made to a PAP to induce the PAP to…arrange for the purchase of the donor's federally reimbursable items, the [AKS] could be violated." The OIG also stated that that independent charities were prohibited from "giv[ing] a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP."

71. In addition to the AKS, several states, including but not limited to Texas, Florida, Illinois, California, and Minnesota, have statutes that prohibit the same type of conduct. Many of

these statutes also prohibit the submission of claims tainted by kickbacks to both government and non-government insurers, even outside the context of government insurance programs. And state common law doctrines can prohibit the conduct as well.

72. In addition to the AKS, the federal False Claims Act (31 U.S.C. § 3729) prohibits knowingly causing the submission of fraudulent claims for payment to a federal health program like Medicare. Pursuant to 31 U.S.C. § 3729(a), claims for reimbursement to the Medicare program that result in violation of the federal Anti-Kickback statute constitute *per se* violations of the False Claims Act.

REGENERON'S SCHEME

73. Regeneron devised and implemented an unlawful scheme designed to interfere with, undermine, and defeat the cost-sharing obligations contained in payors' health benefit plans.

74. Regeneron coordinated with CDF to carefully calculate the exact amount that it needed to pay to CDF to cover Eylea patients' cost-sharing obligations. Regeneron then covertly funneled those amounts through CDF to Eylea patients to eliminate their Eylea cost-sharing obligations.

75. Regeneron enlisted a company called the Lash Group to publicize the availability of these laundered funds in order to induce Eylea prescriptions, connect Eylea patients with CDF, and facilitate payments for Eylea treatments by payors like Humana.

76. Regeneron engaged in this conduct to ensure that the cost-sharing provisions in Humana's plans would not prevent or restrain patients or their physicians from using Eylea, or put downward pressure on Eylea's price.

77. Regeneron's payments constituted illegal kickbacks, and its coordinated conduct with CDF interfered with Humana's plans and violated the laws and restrictions regarding unlawful remuneration and fraud, discussed above.

78. Because of and through its unlawful conduct, Regeneron was able to charge significantly higher prices for Eylea and extract hundreds of millions of dollars from Humana.

79. Documents made public by the DOJ, discussed below, show how Regeneron devised and carried out its scheme.

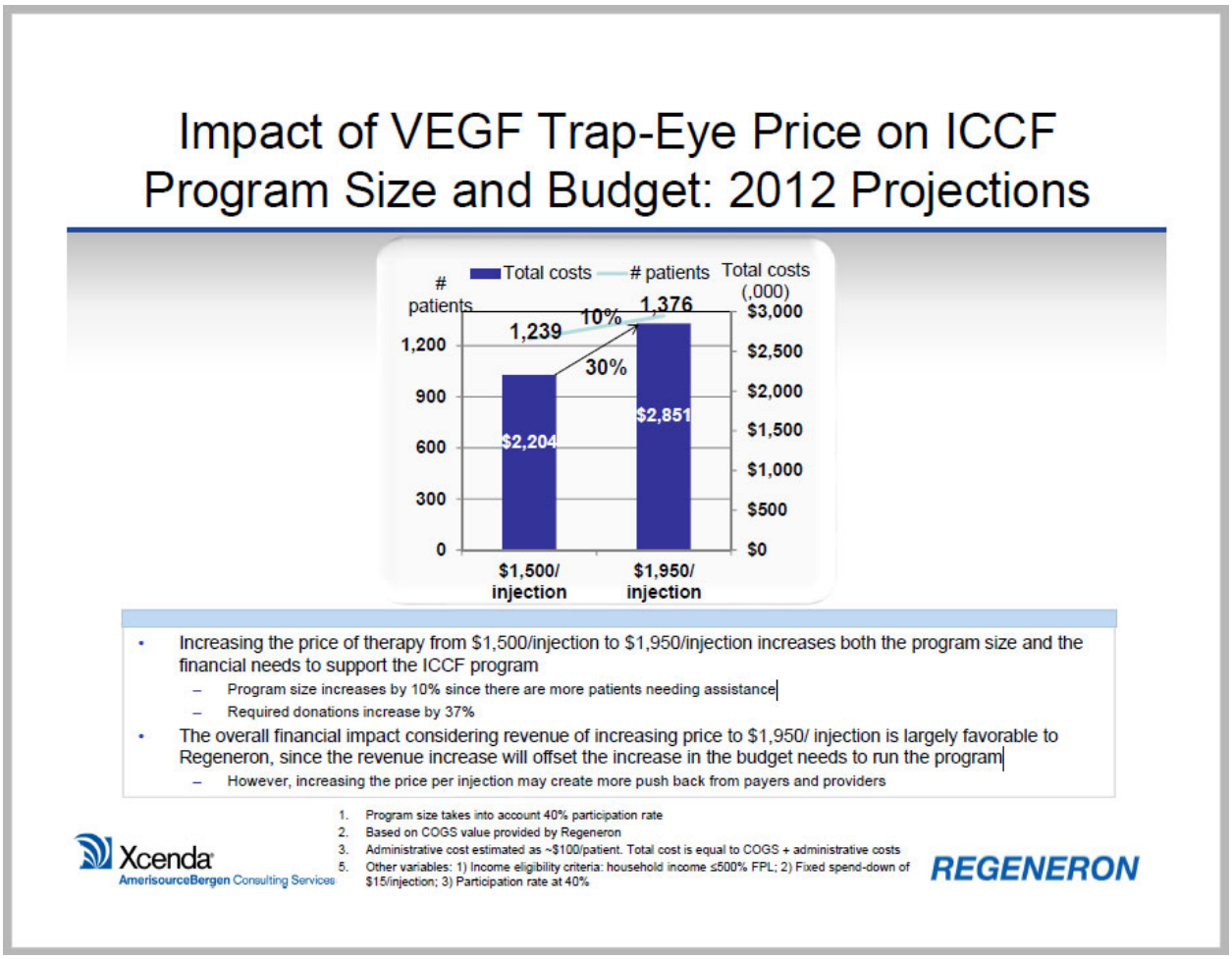
Regeneron Learned that it could Raise Eylea's Price if Patients' Cost-Sharing Obligations were Paid through a Charity

80. In the months that preceded the FDA's approval of Eylea, Regeneron retained Xcenda, a division of the AmerisourceBergen Corporation, to help Regeneron bring Eylea to market. Among other things, Xcenda analyzed the ways in which Regeneron could price Eylea and how forming a relationship with organizations holding themselves out as patient "charities" would allow Regeneron to increase the price of Eylea. Ultimately, Xcenda's work was reflected in a May 12, 2011 presentation to Regeneron. *See* Ex. 2. As evidenced by the presentation, Regeneron was considering pricing Eylea at $1,500 per dose, but by forming a relationship with a patient "charity," Regeneron might be able to increase the price of Eylea to as much as $1,950 per dose.

81. Specifically, Xcenda explained that the vast majority (77%) of patients who were suffering from wet AMD were Medicare beneficiaries, and estimated that Regeneron would need to pay $3 million in 2012 to cover the aggregate cost-sharing obligations of these patients. By paying this sum through a patient charity, however, Regeneron could increase the price of Eylea, and the "financial impact" of increasing [the] price" of Eylea "to $1,950/ injection [would be] largely favorable to Regeneron." Xcenda further explained that the higher price would impose even greater cost-sharing burdens on patients, and that Regeneron would need to devote even more funds to the patient charity, "since there [would be] more patients needing assistance" at the higher price. But Xcenda emphasized that even if Regeneron's "[r]equired donations

increase[d] by 37%," those donations would generate an even greater return on investment, stating that the "revenue increase will offset the increase in the budget needs to run the [patient charity] program." Ex. 2 at 41.

82. The following is an image of this slide:



Ex. 2 at 41

83. Xcenda also informed Regeneron that certain barriers stood between Regeneron and greater profits such as the strict "federal restrictions" on paying the cost-sharing obligations of Medicare patients – restrictions that included prohibitions on financial coordination between Regeneron and patient assistance charities. And Xcenda told Regeneron that one of the "Cons"

associated with using a patient charity to fund patient cost-sharing obligations was the possibility of "[u]nknown allocation of funds among products in the same therapeutic space." Ex. 2 at 30. In other words, if Regeneron truly donated funds to a bona fide independent charity, Regeneron's donations could be used to help patients regardless of whether the patients used, purchased, or were prescribed Eylea—*i.e.*, not just Eylea patients. Along those lines, Xcenda told Regeneron that "[d]onations to copay charities have several limitations, such as . . . limited data provided by the foundation, and no control over operations of the fund (eg, income eligibility criteria or spend-down)." Ex. 2 at 57.

84. Nevertheless, Xcenda concluded that using patient assistance charities still presented "the most financially viable" option for Regeneron. *Id.* In particular, using patient charities would allow Regeneron to increase profits, whereas using other means of supporting patients with financial needs, like providing free Eylea to patients who could not afford it, would negatively impact Regeneron's profits.

85. Based on Xcenda's analysis, Regeneron priced Eylea at $1,850, nearly 25% higher than it had originally contemplated and 33 times higher than an equally effective competitor drug.

Regeneron Conspired with CDF to Pay Eylea Patients' Cost-Sharing Obligations

86. Regeneron understood that patients' and physicians' sensitivity to the price of the Eylea were an impediment to Eylea's profitability, particularly as Eylea was competing with Avastin at a fraction of the cost. Cynthia Sherman, Regeneron's Senior Director for Reimbursement at the time Eylea was launched, confirmed in testimony to the DOJ that "people understood that if co-pay assistance was not available for Eylea or Lucentis patients, that patients with wet AMD would end up on Avastin," and "that's why they wanted to have a managed care co-pay program." Accordingly, and consistent with Xcenda's analysis, Regeneron decided to

form a relationship with a patient charity, and specifically decided to pursue a relationship with CDF (today, CDF is called "Good Days").

87. CDF was founded in 2004 and has provided cost-sharing assistance to patients using donations from pharmaceutical companies since 2006. To do so, CDF would approve grants to cover patients' cost-sharing obligations for specific drugs being used to treat certain chronic health conditions. The grants would be drawn from discrete funds dedicated to treating those health conditions. Physicians administering drugs to treat those conditions would submit claims to CDF for the portion of the drug's cost borne by the patients, and CDF would pay the physicians directly. If funds that covered specific conditions were depleted, cost-sharing assistance from CDF for that condition would become unavailable.

88. In 2011, CDF had approved a fund to cover the cost of treating AMD using the drugs Eylea and Lucentis. Avastin was not approved for CDF assistance. Accordingly, because CDF funding was available to eliminate the cost-sharing obligations associated with Eylea and Lucentis, those drugs appeared cheaper than Avastin from the perspective of patients, even though Eylea was actually much more expensive.

89. Cynthia Sherman testified to the DOJ that "Regeneron did not want to pay for Lucentis's co-pay." Thus because CDF was making funds available for both Eylea and Lucentis, Regeneron initially took a conservative approach, donating only $600,000 to CDF in 2012." But Eylea's success created significant demand for assistance from CDF, and in 2012 Regeneron devised a scheme that would allow it to coordinate with CDF in such a way that the money Regeneron paid to CDF would only be used to benefit patients using Eylea, and not other drugs. Records made public by the Department of Justice convey as much.

90. On July 9, 2012, Regeneron's Senior Manager for Reimbursement and Managed Markets Marketing, Robert Krukowski, emailed a Regeneron staff member named William Daniels and asked if CDF's Executive Director, Clorinda Walley, had "mentioned anything along the lines [of] [Regeneron] upping [its] contribution in 2013" during recent conversations with Daniels. Krukowski stated that Regeneron "probably should up [its] overall contribution to CDF given [Eylea's] performance," but that it would be "hard to pick a number." Ex. 3.

91. On July 23, 2012, Daniels emailed Walley and asked if she would speak with him to "review the numbers" in advance of an upcoming meeting where he would have to "justify [his] request for [Regeneron's] 2013 donation" to CDF, and Walley agreed to meet for that purpose. Ex. 4.

92. The next day, Walley sent Daniels an email entitled "Regeneron Projections 2013" that included a spreadsheet with the same title. The spreadsheet set forth how much CDF was spending on Eylea patients and included projections regarding the amount of money CDF would need to cover the cost-sharing obligations of only Eylea patients in 2013. Ex. 5. Following that communication, CDF effectively began invoicing Regeneron for "donations" illegally tailored to cover the cost-sharing obligations of Eylea patients. Daniels forwarded the same email and spreadsheet to Krukowski, stating that CDF's "2013 projection is pretty much our 2012 actuals." *Id.*

93. Ultimately, Daniels ended up combining the information sent by CDF with Regeneron's internal business information to revise CDF's projections downward. Daniels determined that Regeneron could fund the cost-sharing obligations of existing Eylea patients with payments of approximately $5.6 million, and the cost-sharing obligations of new Eylea patients with payments of between $11.5 and $19.2 million. Ex. 6. Daniels further estimated that

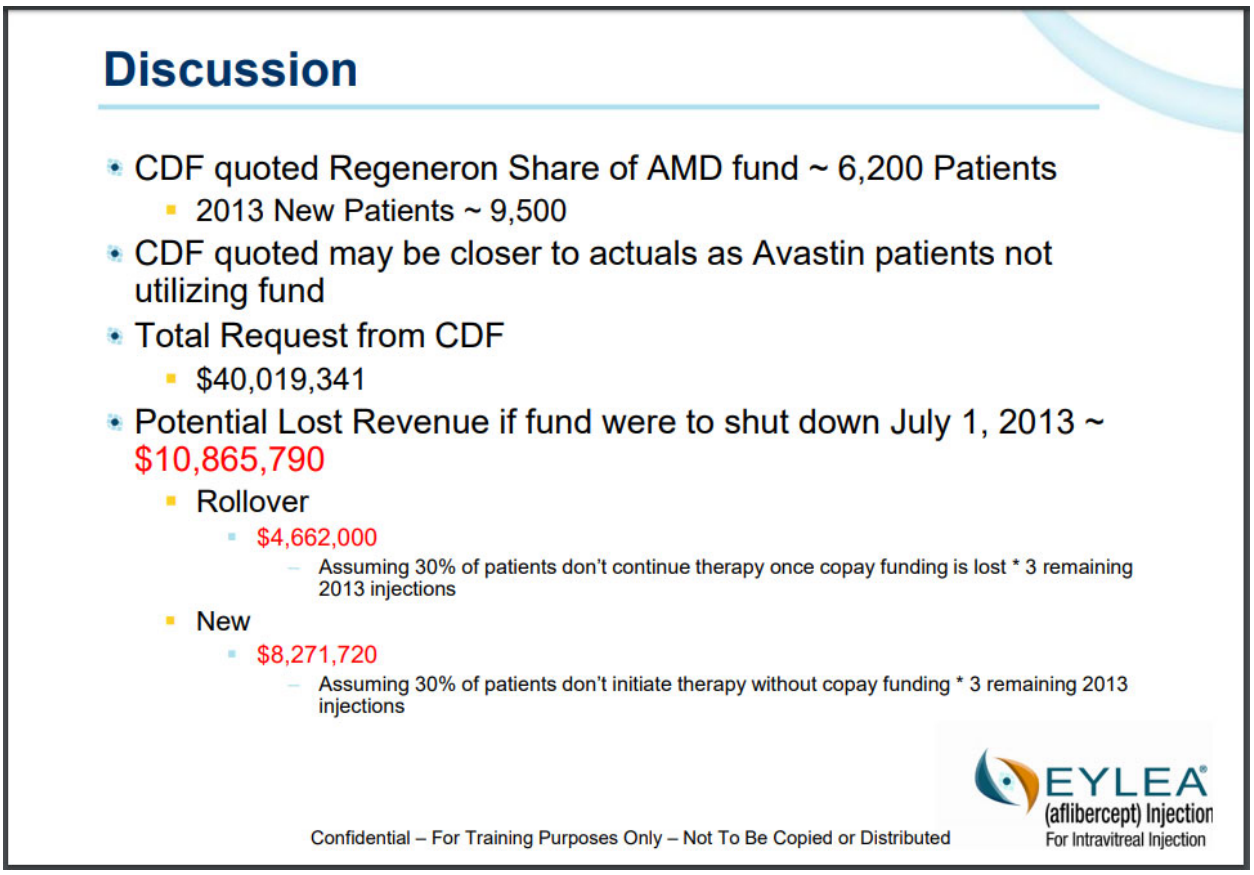
simply by making payments to fund the cost-sharing obligations of existing patients, Regeneron could generate a return on investment of approximately $24.8 million. *Id.*

94. Daniels sent his estimates to Krukowski in August of 2012, stating that Regeneron needed "to try and budget as much as possible" for donations to CDF so CDF's fund would not be totally depleted. *Id.* Krukowski replied that Daniels had "some good points" and asked him to put together a presentation that could be shared with Regeneron's executives that would show what would happen "if CDF isn't funded for a portion of the year[.]" *Id.* Krukowski then scheduled a meeting regarding the "ROI" and "risks" associated with CDF donations with Daniels and Robert Terifay, a Regeneron Vice President. Ex. 7.

95. On August 16, 2012, Daniels sent Krukowski and Regeneron's Executive Director and Head of Trade, Robert Davis, a summary of the situation Regeneron faced regarding its 2013 donation to CDF. Daniels' summary included a chart that compared CDF's projections with his "Regeneron Modified Estimate of CDF Need." Ex. 8. The chart noted that Regeneron's failure to adequately fund CDF could result in millions of dollars in "potential lost sales." *Id.*

96. On August 27, 2012, Daniels sent a presentation to Krukowski that reiterated parts of his previously-sent summary and chart, including the fact that "CDF management has communicated that for 2013, if every donor doesn't cover their market share the fund will be

closed." Ex. 9. The presentation stated that Regeneron might lose millions of dollars in potential revenues if it did not adequately fund CDF. The slide conveying as much is reproduced here:



Ex. 9

97. Shortly before the CDF "ROI" and "risks" meeting between Daniels, Krukowski, and Terifay concerning Regeneron's 2013 CDF donation was scheduled to occur, Daniels sent around a revised presentation that increased the "[p]otential lost revenue" if CDF were not adequately funded. Ex. 10. When the meeting occurred on October 8, 2012, Terifay rejected Daniels' assessment and instead expressed that Regeneron would donate only $2.5 million to CDF. Daniels conveyed that to Walley. Ex. 11.

98. On December 19, 2012, Walley responded by email that a $2.5 million donation would be insufficient and that the fund would likely run out by the end of January 2013. Ex. 11.

Walley included a spreadsheet entitled "Regeneron Projections 2013_1219212" that set out a revised estimate reflecting that Regeneron would need to donate $24,843,956 to cover the cost-sharing obligations of patients using Eylea. *Id.* Again, CDF encouraged Regeneron to make payments to CDF carefully calculated and illegally tailored to cover the cost-sharing obligations of Eylea patients.

99. Later that same day, Krukowski sent an email to Regeneron's Senior Director for Reimbursement Strategy, Cathy Casey, voicing concern about the inadequacy of Regeneron's CDF donation, stating that CDF had provided Regeneron with additional information, and expressing that "we really need to make everyone aware of the risks and what is our true commitment." Ex. 12. By that time, Terifay had agreed to increase Regeneron's payment to $10 million, but Krukowski still felt "confident that we still have an issue at $10 mil based up[on] what CDF is stating and has shared with us." *Id.*

100. On January 3, 2013, Krukowski, Daniels, and Casey met with Terifay to discuss the "new information" Regeneron had received from CDF. Ex. 13. After the meeting, Krukowski sent an email to Walley stating that Daniels had used the information from CDF to inform Regeneron executives, including Terifay, that Regeneron "potentially need[ed] ~25Mil to adequately fund our patient responsibility for 2013" and that Terifay "finally underst[ood] what [Regeneron's] total funding commitment w[ould] be for this year." Ex. 14. Krukowski further wrote that Terifay planned to present the information Regeneron had received from CDF to other Regeneron executives, who he referred to as "the boys." *Id.*

101. On January 4, 2013, Regeneron's Vice President of Financial Planning, Christopher Fenimore, wrote an email to Terifay and others stating that Terifay had "walked [him] through

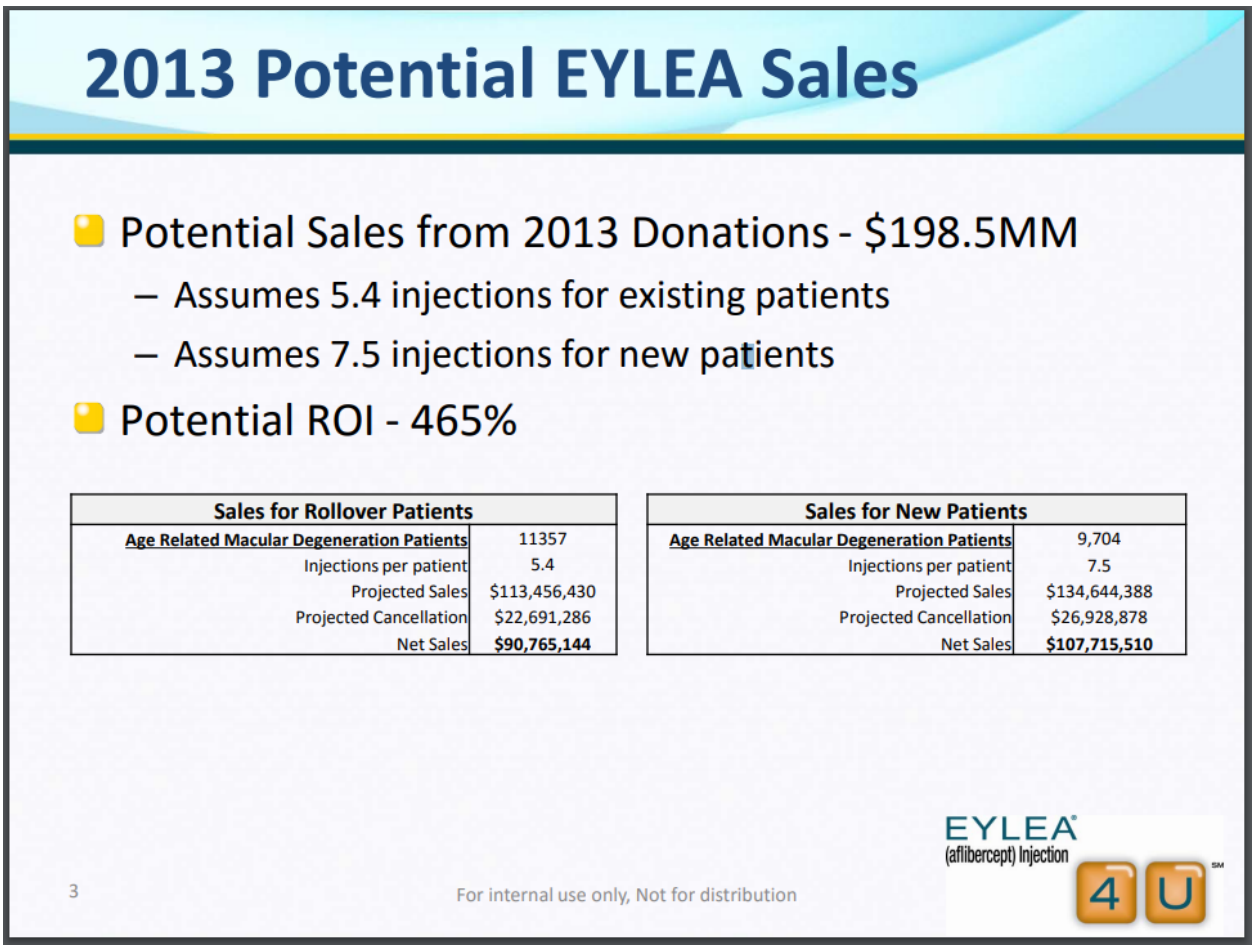
the logic" and that Regeneron's executives had agreed to pay a 2013 donation of $25 million to CDF, i.e., almost the exact amount that CDF had requested. Ex. 15.

102. Regeneron agreed to pay this amount because CDF indicated that funds would be allocated solely to the cost-sharing obligations of patients using Eylea, and not to the cost-sharing obligations of patients using other drugs. Regeneron would not have agreed to pay this amount, or future amounts, if it had not reached an understanding with CDF that CDF would use Regeneron's payments to cover the cost-sharing obligations only of patients using Eylea, and not any other drugs.

103. Regeneron and CDF also had an understanding that the aggregate amounts Regeneron paid to CDF would correlate closely, if not exactly, with the aggregate amounts that CDF would pay out to cover the cost-sharing obligations of Eylea patients.

104. In the first half of 2013, Regeneron "donated" half of its promised $25 million to CDF, sending $5 million on February 13 and $7.5 million on May 1. But as the year progressed, it turned out that even $25 million would be insufficient to cover the cost-sharing obligations of Eylea patients, and on June 18, 2013, Walley sent "updated projections" to Daniels, showing that CDF would actually need $34,540,204 to fully fund the cost-sharing obligations of patients using Eylea in 2013. Ex. 16.

105. On June 24, 2013, Daniels sent a presentation to Krukowski that used the information CDF had provided to explain why Regeneron needed to increase its total 2013 payment to $35 million. The presentation stated that CDF had "paid out $32.6MM through 6/3/13," with 41 percent of that attributable to Eylea. Ex. 17. One slide estimated that "Potential Sales from 2013 Donations" had already totaled "$198.5MM" and that Regeneron enjoyed a "Potential ROI" of "465%" on these donations. *Id.* This slide is reproduced below.



Ex. 17 at 4.

106. On June 26, 2013, Daniels provided this presentation to Fenimore, after which Fenimore forwarded it to Regeneron's Chief Financial Officer, stating "this makes sense to me." Ex. 18. Later that day, Regeneron's Director of Commercial Finance, Stephen Dressel, wrote an email to Daniels stating that Regeneron would increase its 2013 total payment to $35 million—the amount CDF had requested. Ex. 19. On July 9, 2013, Fenimore confirmed to Regeneron's CFO that the $35 million would be paid to CDF. Ex. 20.

107. Regeneron carried out this commitment, paying $7.5 million to CDF on August 21, $10 million to CDF on September 25, and $5 million to CDF on October 1, making its total payments for 2013 equal to the $35 million that CDF had requested.

108. Regeneron continued coordinating with CDF in 2014. On January 3, 2014, Krukowski sent Daniels an email about coordinating with CDF in 2014, and Daniels responded that he had spoken with Walley and "should have her Q1 request" later that day. Ex. 21. Daniels then sent Krukowski and others an email he had received from Walley that included a spreadsheet estimating the amount that CDF would require to fund patients using Eylea—and only those patients—for 2014. Ex. 22. Walley's email included the following summary of requested funds.

> Please find attached an updated AMD projection need for 2014 which includes CDF's need to facilitate assistance for renewal and new patients in the 1st quarter. I have summarized below.

2014 Renewals	$ 29,434,885
2013 Roll-Over	$ 9,500,000
Total 2014 ReEnrollment Need	$ 19,934,885
Total 2014 1st Qtr Need	$ 5,495,226
Sum of Need Existing/New 1st Qtr 2014	$ 25,430,111

Ex. 22

109. Daniels' email also summarized CDF's rationale for its request, noting that funds leftover from Regeneron's "donations" in 2013 would "roll over" into 2014, bringing CDF's total funding request for the first quarter of 2014 to $25,430,111. And Daniels explained that CDF had asked Regeneron to donate a total of approximately $39 million in 2014. Ex. 22.

110. On January 6, Daniels wrote an email to Terifay and others, formally recommending that Regeneron pay CDF $25.5 million in 2014, which was almost the exact amount that CDF had requested. Daniels recommended that the payments be made in two installments of $12.75 million each during the first quarter of 2014. Ex. 23.

111. On January 10, 2014, Regeneron executives approved the first installment payment, (*see* Ex. 24), and Regeneron made a $12.5 million payment to CDF on January 15, 2014.

112. During this time, the amounts Regeneron paid in to CDF correlated almost exactly to the amounts CDF paid out for patients using Eylea—and the amounts for which CDF effectively invoiced Regeneron—confirming that CDF served as a financial conduit between Regeneron and patients using Eylea.

113. Daniels ultimately provided sworn testimony to the DOJ that he understood CDF would use the amounts Regeneron was paying solely to cover the cost-sharing obligations of patients using Eylea.

114. Due to increased scrutiny of such kickback scheme like that described above, after 2014, Regeneron was more careful to avoid creating such an obvious written record of its illegal relationship and coordination with CDF.

115. But Regeneron knew that it needed to maintain this unlawful relationship with CDF in order to maintain Eylea's inflated price, and consequently, Regeneron's increased profits. Indeed, just one day before Regeneron's executives approved the January 2014 payment of $12.5 million, a Regeneron sales associate sent an email to Daniels and Krukowski stating that a large provider had heard that CDF had run out of money for Eylea, and that, as a result, the provider had begun "putting patients only on Avastin," which would mean lost sales for Regeneron. Ex. 25. Regeneron thus knew that if it did not use CDF to cover its patients' cost-sharing obligations, its anti-VEGF drug priced at $1,850 per dose could not compete with an equally effective drug priced at only $55 per dose.

116. Accordingly, as discussed below, the scheme continued long after 2014.

117. On information and belief, Regeneron took specific overt acts during the relevant period to perpetuate its unlawful scheme, including: (a) obtaining information from CDF regarding patients using Eylea, including Humana members, along with information regarding

the amounts of money that were needed to eliminate the patients' relevant cost-sharing obligations, (b) calculating the specific amounts that Regeneron needed to pay to CDF, which were designed to correspond to, and cover, the cost-sharing obligations of the patients using Eylea, including Humana members, (c) confirming that the amount of revenue that Regeneron would amass by funneling payments through CDF to patients would far exceed the sum of the payments to CDF, (d) making massive payments to CDF to carry out the unlawful scheme, and (e) ensuring that CDF used those payments to cover the cost-sharing obligations only of patients using Eylea, including Humana members.

118. Moreover, on information and belief, CDF also took specific overt acts during the relevant time period to perpetuate this unlawful scheme, including: (a) providing information to Regeneron regarding patients using Eylea, including Humana members, including the amount of funds necessary to eliminate the patients' relevant cost-sharing obligations, so that Regeneron could use the information to calculate and send massive, corresponding payments, and (b) routing, by way of direct payments to physicians, the sums it received from Regeneron to patients using Eylea, including Humana members, to eliminate their relevant cost-sharing obligations.

119. The concerted and unlawful acts and actions of Regeneron and CDF have directly and proximately caused Humana to incur significant damages in the form of payments made for Eylea that Humana otherwise would not have made.

Regeneron Concealed the Conspiracy

120. Regeneron's leadership knew that the way Regeneron was coordinating with, and using, CDF violated the law. Regeneron employees even warned the company's executives of this.

121. For example, Sherman testified to the DOJ that she warned Regeneron executives, including Terifay and Dressel, that Regeneron could not legally "get a breakdown of [its] spend by EYLEA users" from CDF, "designate [Regeneron's] donations specifically for [Eylea]," or "get actual utilization data from the foundation." Sherman testified that these executives rejected her warnings and insisted on an "overview of who [Regeneron] [was] providing [its] financial assistance to." Robert Davis gave a similar warning to Daniels and Krukowski in October of 2012. And Daniels himself circulated a copy of an OIG opinion[8] forbidding the behaviors discussed above to Krukowski in December of 2012.

122. Knowing that their company's conduct violated the law, Regeneron executives deceived the company's auditors regarding the nature of Regeneron's relationship with CDF.

123. For example, after company auditors sent an email in February of 2013 asking what information Regeneron had received from CDF, Terifay provided a deceptive—but revealing—response, stating that Regeneron "ha[d] no rights to information of any sort on disposition of funds" from CDF, that Regeneron "[could not] ask for any information from the CDF," and that Regeneron merely "gave a charitable donation." Before sending this response, Terifay also manipulated an earlier email in the chain from Daniels to remove evidence of the fact that Regeneron was indeed receiving the very information it should not have been receiving. Ex. 26.

124. In another example, in November 2013, Krukowski and Daniels deceived the company's auditors into believing that Daniels was not having "conversations with CDF concerning product level data." Ex. 27. Krukowski and Daniels then misrepresented that Regeneron had received only aggregate reports from CDF that *did not* contain data specific to

[8] HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

Eylea. To promote this false narrative, Daniels requested, and received, a report from Walley that did not contain Eylea data, then sent it to the company's auditor to create the false impression that Regeneron only received reports from CDF in this format. Exs. 28, 29. Daniels subsequently sent the company's auditor an email wherein he falsely stated that Regeneron did not "receive any other reports or data" other than the report he had previously provided. Ex. 30. Daniel later admitted in sworn testimony to the DOJ that his statement was a lie, and that he made the statement to the company's auditor because he "was told to" by Terifay.

125. On information and belief, Regeneron's executives lied to the company's auditors regarding the nature of Regeneron's relationship with CDF because they knew that if they did not, those auditors might expose or inform others that Regeneron was engaging in illicit and unlawful activity. In doing so, Regeneron's executives also took active steps to conceal the nature of their unlawful conduct and relationship with CDF from Humana and other Medicare payors.

126. On information and belief, the examples discussed above are just some instances of what was a larger course of behavior by Regeneron to actively conceal its unlawful scheme.

127. Moreover, Regeneron worked to actively conceal its scheme because it knew that its unlawful relationship with, and use of, CDF meant that related claims submitted to payors, including Humana, had been tainted with illegal kickbacks and were not payable under both federal law and Humana's benefit plans. Regeneron knew that payors, including Humana, would not pay claims for Eylea treatments if they knew those claims had been tainted by, or were the product of, an illegal kickback scheme.

128. Regeneron also knew that the providers who prescribed and used Eylea to treat patients would submit claims to payors like Humana and, in doing so, would certify that the

claims were not tainted by illegal kickbacks. Regeneron knew that its unlawful relationship with CDF and CDF's use of Regeneron's payments to cover Eylea patients' cost-sharing obligations would render those certifications false.

129. Regeneron knew that Medicare payors like Humana would rely on the certifications in paying the related claims, and intended for that to happen. Regeneron further knew that, by actively concealing its unlawful scheme, it could deceive payors like Humana into paying massive sums on claims for Eylea treatments, which would translate into massive sales and revenues for Regeneron.

Regeneron Used its Scheme to Induce Physicians to Prescribe Eylea

130. As discussed above, physicians consider how much their patients will need to pay for drugs in deciding which drugs to prescribe to those patients to treat their conditions. Indeed, physicians did this with respect to the drugs at issue here, prescribing Avastin to their patients when they determined that, if they prescribed the much more expensive Eylea, patients would bear the cost of that drug.

131. Regeneron was aware of this dynamic as well, and had remarked that physicians would begin "putting patients only on Avastin" if they believed those patients would otherwise have to bear Eylea's cost. *See* Ex. 25.

132. Thus, in order to prevent this from happening, Regeneron promoted the fact that "charitable" funding was available from CDF to cover cost-sharing obligations associated with Eylea, all while concealing the role it was playing in funding and funneling money through CDF to be used for patients using Eylea.

133. Indeed, in or around 2012, Regeneron launched a program that it called "EYLEA4U" which was designed to maximize the sales of Eylea, including by ensuring that patients using Eylea do not bear the cost of the drug.

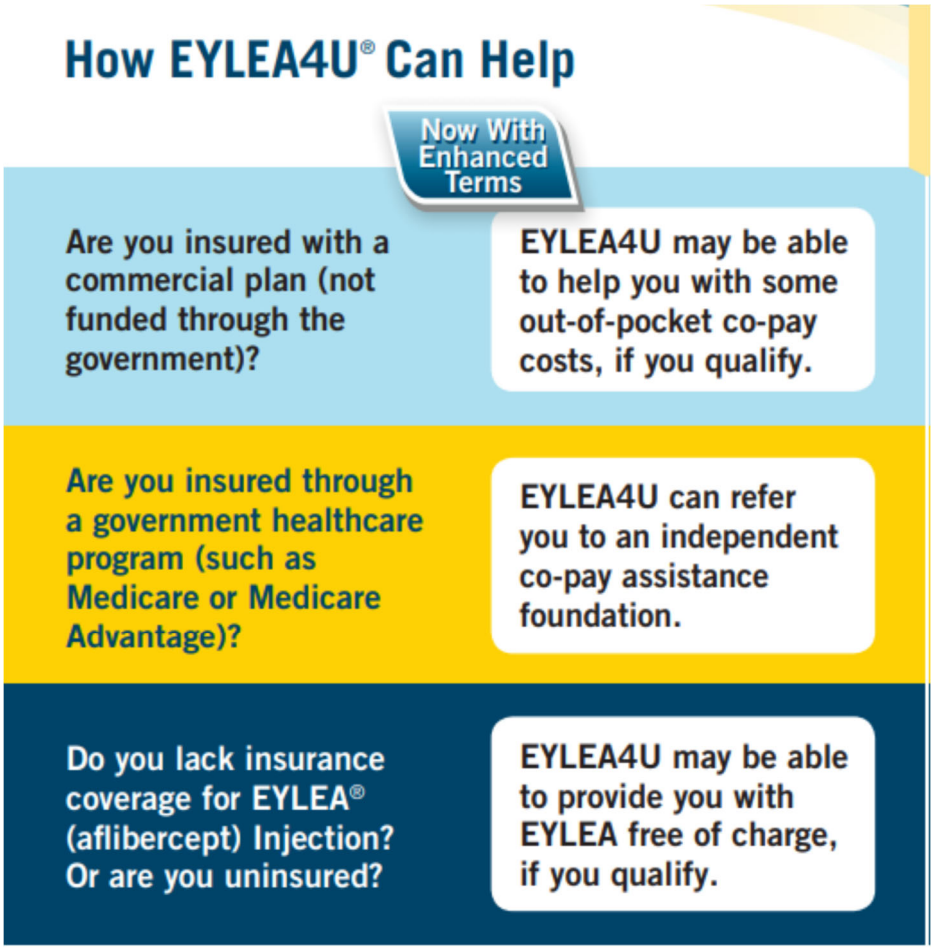
134. Regeneron selected contractors from a company called the Lash Group to help run the EYLEA4U program. The Lash Group was a sister company to Xcenda—the company that had helped Regeneron devise its scheme in the first place. On information and belief, the Lash Group created, implemented, and operated the EYLEA4U program as described below. The Lash Group thus became a third member of the conspiracy and a vital component of its operation.

135. The Lash Group marketed and directed the EYLEA4U program toward physicians who were in a position to prescribe Eylea to patients, and promoted it as a way to "[h]elp[ ] to meet the reimbursement and copay assistance needs of you and your patients." Ex. 31 at 2.

136. Physicians would then send information about patients' plans to the EYLEA4U program before the patients began using Eylea, and EYLEA4U would use the information to "determine if [the patient] [was] eligible to participate in Regeneron's reimbursement assistance program, patient assistance program and other support programs (together, 'EYLEA4U® Programs')." Ex. 32 at 2.

137. On information and belief, the EYLEA4U program would refer most or all of the Medicare patients to CDF to receive "charitable" cost-sharing assistance.

138. In using EYLEA4U to refer patients to CDF, Regeneron (through materials distributed by the Lash Group) used materials like the brochure below that falsely stated CDF was "an independent co-pay assistance foundation."



Ex. 33 at 3.

139. Regeneron also made false statements on various websites and in its promotional materials that "Regeneron does not influence or control the operations of patient assistance programs through independent charitable foundations." Ex. 34 at 2.

140. Regeneron publicized false statements like this to patients, physicians, and the general public, all while omitting information about the true nature of its relationship with and use of CDF, to keep the unlawful kickback scheme it was carrying out with CDF hidden.

141. EYLEA4U also actively worked to connect patients using Eylea with CDF, and then worked with CDF to ensure that the patients would receive money from CDF that Regeneron had "donated." Indeed, with respect to Medicare patients that the EYLEA4U program referred to

CDF, EYLEA4U would follow up with CDF "until a decision [was] made on [the patient's] application, and would then "[l]et [the patient's] doctor's office know that [the patient] ha[d] applied and provide an update with the final decision." Ex. 33 at 6.

142. In addition to connecting Eylea patients with CDF funding that Regeneron had supplied, EYLEA4U also assured physicians that funds would be available to cover the cost-sharing obligations of patients who had been prescribed Eylea. Because of these efforts, physicians knew that if they prescribed Eylea to specific patients, EYLEA4U would make sure that the patients qualified for CDF funding. This knowledge affected physicians' decisions regarding whether to prescribe Eylea or its much lower-priced competitor drug, Avastin.

143. CDF also provided information regarding the availability of funds to physicians. Specifically, there were "CDF rep[s]" who provided the information to physicians, who then used the information in deciding whether to prescribe Eylea or Avastin. Ex. 25. EYLEA4U knew of, and encouraged, these contacts by sending CDF's contact information to physicians through the EYLEA4U program.

144. On information and belief, because of these efforts, it became widely known among prescribing physicians, including among physicians who did not have contact with the EYLEA4U program, that there was "charitable" funding available through CDF to cover Eylea patients' cost-sharing obligations.

145. The fact that this funding was available through CDF to cover patients' cost-sharing obligations affected, and was material to, physicians' decisions to prescribe Eylea and patients' decisions to use Eylea, rather than Avastin. Indeed, when this funding was not available, most physicians and patients chose to prescribe and use Avastin over Eylea.

146. Regeneron's conduct, including its unlawful relationship with CDF, its promotion of available funding, and its work to connect patients with CDF funds, induced physicians to prescribe, and patients to use, Eylea.

147. By funding, and therefore eliminating, the cost-sharing obligations associated with Eylea, Regeneron made Eylea "cheaper" to patients than its competitor, Avastin. Physicians prescribe Avastin rather than Eylea when patients have to pay cost-sharing obligations because most patients can afford the cheaper Avastin which also is equally effective as Eylea. But once physicians realized that Eylea could be "cheaper" to patients than Avastin, they prescribed Eylea.

148. Physicians are also motivated by their own economic incentives, and know that they typically get paid more money by payors like Humana on claims that are for Eylea treatment versus claims that are for Avastin treatment. Once physicians realized that their patients could actually "afford" Eylea because of Regeneron's conduct, their economic incentive influenced them to prescribe it over Avastin.

149. Richard O'Neal—Vice President of Market Access at Regeneron—recently filed a declaration in federal court attesting to the fact that doctors will prescribe Avastin to their patients if Eylea prescriptions become unprofitable.[9] O'Neal explained that, in light of a new regulation that could lower the Medicare reimbursement rate for Eylea below what Regeneron charged for the drug, Regeneron had "begun receiving questions from doctors and organizations that advocate on behalf of doctors regarding the imminent lower reimbursement rate for EYLEA and the looming need to switch patients from EYLEA to off-label Avastin." O'Neal elaborated

[9] *See* Declaration of Richard O'Neal in Support of Plaintiff's Order to Show Cause for Preliminary Injunction, Temporary Restraining Order, and Expedited Briefing Schedule (Dkt. 13), *Regeneron Pharmaceuticals, Inc. v. U.S. Department of Health and Humans Services*, Case No. 7:20-cv-10488 (S.D.N.Y. Dec. 11, 2020).

further that, even if the regulation "w[as] eventually enjoined and reimbursement rates for EYLEA returned to their current levels, at least some patients who were switched from EYLEA to off-label Avastin (or other drugs) would be unlikely to return to EYLEA." As a result, "to avoid sales lost to off-label Avastin[,] . . . Regeneron would be forced to lower the price of EYLEA," which would lead to "reduced revenue for Regeneron."

150. Patients also base their decisions about what drugs to use in part on how much using the drug will cost them. Once patients learned, because of Regeneron's conduct, that funding was available to render Eylea "cheaper" than Avastin, that also influenced their decisions to agree to use and undergo treatment with Eylea, rather than the normally much cheaper Avastin.

151. Regeneron devised and carried out its scheme intending for at least the foregoing factors to induce physicians to prescribe, and patients to use, Eylea. Indeed, Regeneron devised and carried out its scheme because Xcenda had indicated that, by using a "charity" to eliminate patients' cost-sharing obligations, Regeneron could induce the prescription and use of Eylea even if it charged artificially high prices for the drug. Regeneron's "ROI" analyses further confirm that it knew its scheme would induce physicians to prescribe, and patients to use, Eylea.

Regeneron Worked to Ensure that Payors Paid Claims for Eylea

152. Although Regeneron sold Eylea directly to wholesalers, it knew that its ability to sell Eylea depended on payors reimbursing claims submitted for Eylea treatments. Indeed, without such payments, there would be no market for the drug. Regeneron acknowledged as much, stating, for example, in United States Securities and Exchange Commission ("SEC") filings that "[s]ales in the United States of [Regeneron's] marketed products are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare programs, health maintenance organizations, pharmacy benefit

management companies, and government programs such as Medicare and Medicaid." (*See* 2019 Form 10-K Annual Report at p. 24 (Feb. 7, 2020)).

153. Accordingly, EYLEA4U monitored, facilitated, and ultimately ensured that Humana and other payors paid the claims that physicians submitted to those payors for Eylea treatments, including claims tainted by the unlawful kickback scheme.

154. EYLEA4U did this by offering "reimbursement support" services for physicians who it knew were prescribing Eylea. Because the payment of claims depended on the claims being covered by patients' benefit plans, EYLEA4U specifically provided services designed to cause claims to be paid, all while facilitating the scheme described herein.

155. For example, EYLEA4U would conduct a "thorough [benefits investigation] that—within 2 business days—summarizes [the] patient's coverage, [prior authorization] requirements, cost responsibility, and any additional coverage information" related to Eylea. Ex. 35 at 2. Doing this involved contacting payors to confirm that patients' plan benefits covered and would pay for Eylea-related treatments and claims. EYLEA4U would also "recommend[]" to physicians that, "[b]efore a patient starts EYLEA treatment," the physician should "conduct a [benefits investigation] by completing and submitting an EYLEA4U® Enrollment form," which would further permit EYLEA4U to direct that patient to cost-sharing assistance through CDF. Ex. 35 at 1. EYLEA4U would "[r]eview the status of an EYLEA claim with the patient's insurer," and would contact the payor to make sure the payor paid the claim. Ex. 35 at 3.

156. As it operated the EYLEA4U program, the Lash Group shared the information it gathered through benefits investigations with Regeneron.

157. Regeneron thus not only knew that specific provisions of health benefit plans imposed cost-sharing obligations on Eylea patients (including those Humana offers to its

members), Regeneron obtained the specific details of those provisions through the EYLEA4U program.

158. And EYLEA4U would provide "reimbursement support" to physicians who were prescribing Eylea by providing information that would help "prepare" claims and, when claims were denied, "provid[ing] . . . information on how to resolve the issue." Ex. 35 at 2.

159. On information and belief, between 2012 and the present, EYLEA4U representatives contacted Humana on behalf of Regeneron to ensure that Humana paid claims for Eylea as part of the services described above. In doing so, these representatives never informed Humana of Regeneron's unlawful scheme.

Because of its Scheme, Regeneron Obtained Windfall Profits

160. Regeneron's scheme achieved its purpose, allowing Regeneron to maintain an artificially high price for Eylea and obtain windfall profits for many years. Indeed, since 2011, Regeneron has been able generate $22.4 billion in revenue, and massive profits, by selling Eylea at its inflated price, pursuant to the scheme described herein.

161. And Regeneron knew that its overall corporate success depended in large part on maintaining the scheme and the revenues that it allowed Regeneron to obtain. In 2013 statements to the SEC, for example, Regeneron acknowledged that its overall revenues came predominantly from Eylea sales, and that a drop in those sales would cause material harm to the company. (*See* 2013 Form 10-K Annual Report, at p. 20 (Feb. 13, 2014)). Regeneron also acknowledged that other drugs like Lucentis and Avastin were "strong competition," that ophthalmologists were using Avastin off-label to treat wet AMD, and that Avastin's relatively low cost presented a significant challenge to Eylea.

162. The percentage of Regeneron's revenues derived from Eylea sales increased over the years, even as competition increased. For example, in 2015 statements to the SEC,

Regeneron acknowledged that recently approved drugs represented even more competition for Eylea and acknowledged that Eylea's commercial success depended on Regeneron being able to persuade prescribing physicians to keep prescribing Eylea over its competition. (*See* 2014 Form 10-K Annual Report, at p. 23-24 (Feb. 12, 2015)).

163. These risks and dynamics reinforced Regeneron's motivation to continue carrying out, and hiding, its unlawful relationship with and use of CDF.

164. By 2019, Regeneron's success as a company was still heavily dependent on Eylea, and the scheme on which Eylea's commercial success had been built. Indeed, in 2019 statements the SEC, Regeneron acknowledged that it was "substantially dependent" on Eylea, and that "any difficulty with the commercialization of Eylea" would lead to "a reduction in revenue" that would threaten Regeneron's ability "to sustain profitability." (*See* 2019 Form 10-K Annual Report, at p. 27 (Feb. 7, 2020)). Indeed, in 2019, Eylea brought in over $4 billion for Regeneron, accounting for roughly 70% of Regeneron's revenues, which would not have been possible absent the scheme described above.

165. To date, Eylea remains Regeneron's top-selling product.

166. Regeneron was not the only conspirator to profit from the scheme. Regeneron paid Lash Group to operate EYLEA4U, and CDF retained a significant portion of Regeneron's donations (roughly 9%) as "administrative fees." The more Eylea that Regeneron was able to sell through the scheme, the more payments Regeneron would make to CDF, the more money CDF would obtain as administrative fees, and the greater the demand (and, on information and belief, the payments to the Lash Group) for the EYLEA4U program.

167. The scheme described above continued in much the same way after 2014 and, on information and belief, through the present. Among other things:

168. Regeneron continued making large donations to CDF, and as discussed above, avowedly would not make such donations absent assurances from CDF that the funds would be used for Eylea patients, to the exclusion of patients taking other drugs;

169. Eylea patients have continued receiving "charitable" funding since 2014 in much the same way as described above;

170. As explained above, absent the illegal scheme, Regeneron would not be able to maintain Eylea's artificially high price, which remained constant after 2014 and has never dropped;

171. As explained above, absent the illegal scheme, Regeneron would not have been able to maintain its high volume of Eylea sales at the drug's current price, yet Eylea remains the top selling drug of its kind despite cheaper and comparably effective competition; and

172. As explained above, Regeneron's dependence on, and motive to perpetuate, the windfall profits it reaps from sales of Eylea has remained constant or grown since 2014, and these windfall profits are possible only due to the scheme described above.

The United States Department of Justice Investigates and Sues Regeneron for its Scheme

173. In 2014, the United States Department of Justice started applying additional scrutiny to the relationships between pharmaceutical companies and entities that purported to be independent charities. Its efforts resulted in the United States recovering hundreds of millions of dollars related to kickback and false claims schemes between drug companies and purported "charities" like the one described in this Complaint.

174. For example, in 2017 the DOJ announced that a drug company called United Therapeutics Corporation ("UT") had "agreed to pay $210 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking UT's pulmonary arterial hypertension drugs." The DOJ had found that UT had "routinely obtained data from the

foundation detailing how much the foundation had spent for patients on each Subject Drug and that this data was used by UT to decide how much to donate to the foundation."[10]

175. In 2018, the DOJ announced that a drug company called Actelion Pharmaceuticals US, Inc. had agreed to pay $360 million "to resolve claims that it illegally used a foundation as a conduit to pay the copays of thousands of Medicare patients taking Actelion's pulmonary arterial hypertension drugs." The DOJ had found that Actelion "routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug; it then used this information to decide how much to donate to the foundation and to confirm that its contributions were sufficient to cover the copays of only patients taking the Subject Drugs." [11]

176. In 2019, the DOJ announced that CDF—the "charity" at issue in this case—had itself "agreed to pay $2 million . . . to resolve allegations that [it] violated the False Claims Act by enabling pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs." The DOJ specifically determined that CDF had "provided [a pharmaceutical company] with information concerning the number of [its] patients receiving money from CDF's . . . fund," which "made it possible for [the pharmaceutical company] to confirm that CDF was using [its] money primarily to cover co-pays for [its drug], even though other [competing] drugs were on the market."[12]

177. The DOJ had opened an investigation into the relationship between CDF and Regeneron in 2017, and had subpoenaed documents and taken sworn testimony from Regeneron

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[10] Department of Justice, *Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks* (Dec. 20, 2017), https://tinyurl.com/y7xsl95y.
[11] Department of Justice, *Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks* (Dec. 6, 2018), https://tinyurl.com/y67zsuj9.
[12] Department of Justice, *Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients* (Oct. 25, 2019), https://tinyurl.com/y4hjrb7x.

witnesses during the years that followed. These efforts ultimately resulted in the United States filing a lawsuit against Regeneron on June 24, 2020. *See United States v. Regeneron Pharmaceuticals, Inc.,* Case No. 20-cv-11217 (D. Mass.). The United States' Complaint contained detailed allegations and dozens of exhibits that illustrated Regeneron's conduct and the unlawful scheme it has devised, implemented, and concealed.

178. Before the United States' Complaint was filed, Regeneron had successfully concealed its scheme from the public and from Humana.

Regeneron's Scheme Caused Damage to Humana

179. Since 2011, Humana's Medicare and commercial plans paid out more than $900 million on claims for Eylea.

180. On information and belief, Regeneron's scheme caused the vast majority of these payments to be made, which would not have been made in the absence of Regeneron's scheme.

181. Most of the claims Humana paid were in fact not payable because they were tainted by Regeneron's unlawful scheme, including the kickbacks it was paying related to those claims.

182. Attached as Exhibit 36 are specific examples of claims that Humana paid under its Medicare Advantage plans for Eylea, which Humana has confirmed through its own investigation to have been tainted by the scheme described above, and which Humana would not have paid but for the scheme described above. The claims have been anonymized to protect the sensitive health information of the members at issue.

183. Humana is entitled to damages in the amount of payments it made where Regeneron, either directly or through CDF or another third-party conduit, paid Humana members' cost-sharing obligations as part of Regeneron's unlawful scheme.

184. Because of the secretive nature of Regeneron's relationship with, and use of, CDF, which was not made public until June 2020, Humana does not know the full scope of damage caused by Regeneron's unlawful conduct.

TOLLING

185. To the extent any limitations periods might apply to the causes of action Humana has against Regeneron, those periods have not run or started to run because Regeneron has engaged in continuing, repetitive, tortious conduct that has not ceased, causing additional and ongoing injury to Humana

186. Even if one or more limitations periods could apply, they would be tolled by virtue of the discovery rule. Humana only learned of Regeneron's conduct on or about June 24, 2020, when the Department of Justice filed suit against Regeneron. Due to Regeneron's concealment of its scheme, Humana could not have discovered the scheme earlier. Indeed, the very purpose of Humana using CDF as a conduit through which to pay the cost-sharing obligations of Eylea patients was to conceal its unlawful actions.

COUNT I

FRAUDULENT CONCEALMENT AND FRAUD

187. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

188. Regeneron knew that Humana paid claims for Eylea, and that Regeneron's ability to sell Eylea depended in large part on payments being made by payors like Humana.

189. Regeneron possessed superior knowledge of facts that were not available to Humana and that it knew were material to Humana's decision to pay claims for Eylea, including that:

a. Regeneron unlawfully received information from CDF regarding the amounts of money that were needed to cover the cost-sharing obligations of Eylea patients only;

b. Regeneron unlawfully used this information to calculate and make payments to CDF, characterized as "donations," that were designed to cover the cost-sharing obligations of Eylea patients only;

c. Regeneron and CDF unlawfully coordinated with each other to ensure that the payments Regeneron made were distributed to Eylea patients, and that the amount of money Regeneron paid to CDF had a one-to-one relationship with the amount of money CDF spent on Eylea patients on at least an annual basis.

d. CDF did not act as an independent and *bona fide* charity, but rather as a conduit Regeneron used to eliminate the cost-sharing obligations of Eylea patients who were enrolled in Humana's Medicare plans;

e. The effect of Regeneron's conduct was that the cost-sharing obligations of most or all Eylea patients were effectively waived;

f. By using its relationship with CDF to eliminate the cost-sharing obligations of Eylea patients, Regeneron was able to inflate the price of Eylea;

g. Regeneron used its unlawful arrangement with CDF to induce physicians to prescribe, and patients to use, Eylea; and

h. But for Regeneron's unlawful arrangement with CDF, patients would have been treatment with Avastin rather than Eylea, or Regeneron would have had to substantially lower the price of Eylea to compete with Avastin.

190. Humana was not aware of any of these facts.

191. These facts were material to Humana's decision to pay claims for Eylea pursuant to its Medicare plans. The facts rendered claims for Eylea that had been submitted to Humana not

payable under federal law, and had Humana known of those facts, it would not have paid claims for Eylea that had been tainted by Regeneron's unlawful conduct.

192. Regeneron knew that Humana did not know of these facts and would not have paid claims for Eylea if it learned of them.

193. Regeneron also knew that claims submitted by providers to Humana for Eylea would certify that the claims were not tainted by illegal kickbacks, and that its relationship with and use of CDF violated the federal AKS and rendered those certifications false.

194. Regeneron knew that Humana relied on the certifications in paying claims for Eylea and did not know that the certifications were false.

195. Both Regeneron's superior knowledge of the facts discussed above and its active concealment of its unlawful conduct with the intent to deceive independently gave rise to a duty to disclose those facts to Humana.

196. Regeneron did not disclose any of those facts to Humana.

197. Indeed, despite regularly contacting Humana to monitor and facilitate payment of claims for Eylea, Regeneron failed to disclose those facts in order to deceive Humana into paying claims under its Medicare plans that were tainted by illegal kickbacks.

198. Regeneron also took affirmative steps to conceal those facts.

199. Regeneron knew that by concealing its scheme, it could deceive Humana into paying claims for Eylea that Humana would not otherwise pay.

200. Humana reasonably believed that Regeneron was not engaged in an illegal scheme with CDF, and that the claims submitted to Humana's Medicare plans were not tainted by illegal kickbacks.

201. Humana reasonably relied on those beliefs in paying claims for Eylea.

202. As a result of Regeneron's fraudulent concealment, Humana was damaged by paying millions of dollars on claims for Eylea submitted to its Medicare plans that should not have been paid.

203. Regeneron also made affirmative misrepresentations regarding the nature of its relationship with CDF through websites and in promotional materials related to Eylea.

204. Regeneron specifically misrepresented that CDF was "an independent co-pay assistance foundation" and that "Regeneron does not influence or control the operation of patient assistance programs through independent charitable foundations," along with other similar public misrepresentations.

205. Regeneron knew these representations were false and took steps to actively conceal facts that would illustrate their falsity, as described above.

206. Regeneron intended for payors, including Humana, to rely on and be deceived by its misrepresentations regarding the nature of its relationship with and use of CDF.

207. And Regeneron knew that if payors, including Humana, knew the true nature of Regeneron's relationship with and use of CDF, they would not pay claims for Eylea that had been submitted to their Medicare plans.

208. Humana reasonably relied on Regeneron's misrepresentations.

209. As a result of Regeneron's misrepresentations, Humana was damaged by paying more than $900 million on claims for Eylea submitted to its Medicare plans.

210. On information and belief, the illegal kickback scheme between Regeneron and CDF tainted most or all of the claims for Eylea that were submitted to Humana and its Medicare plans between 2013 and the present.

211. By virtue of the foregoing, Humana is entitled to recover compensatory and punitive damages in an amount to be determined at trial.

COUNT II

TORTIOUS INTERFERENCE WITH CONTRACT

212. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

213. Humana's members are parties to Humana's benefit plans which are contracts between Humana and those members.

214. Humana's benefit plans, including its Medicare Advantage and Medicare Prescription Drug plans, require Humana members to pay the cost-sharing obligations when using prescription drugs, including Eylea.

215. Humana's Medicare Advantage health plans state, for example, that it is the member's responsibility to pay what their cost sharing, including their "share of the cost when [they] get the service or drug."

216. Humana's Medicare Part D plans similarly state that only when a member pays for their cost sharing themselves do those payments count towards their out-of-pocket costs. The plans further state that Humana will not pay any share of the cost of a drug

217. Regeneron knew that Humana members were parties to Humana's benefit plans and that those plans required the members to pay cost-sharing obligations when using prescription drugs, including Eylea. Indeed, those requirements are standard features of plans, and the very mechanisms and barriers that Regeneron wanted to undermine with its scheme. Regeneron was not only aware of these terms of Humana's contracts with its members, but devised the scheme described herein to subvert those contractual terms.

218. Moreover, because Regeneron's representatives regularly contacted payors like Humana to determine the "cost responsibility" of specific patients for Eylea under the EYLEA4U program, it knew the specific amounts of money that specific patients owed in many instances. Regeneron understood that the cost-sharing obligations discussed above were terms of contracts that Humana maintained with its members.

219. In an effort to subvert and defeat the substance and function of the Humana plan provisions that required members to pay cost-sharing obligations, Regeneron intentionally interfered with those plan provisions by using CDF as a conduit through which Regeneron paid for and eliminated Humana's members' cost-sharing obligations, by paying those obligations directly to providers. Regeneron paid and funneled money through CDF so that it could conceal its tortious conduct and the fact that *it* was the source of the funds that were being used to eliminate Humana's members' cost-sharing obligations.

220. Regeneron's conduct and interference caused Humana's members to breach their agreements with Humana when they failed to pay the cost-sharing obligations that Humana's benefit plans required.

221. Regeneron's interference was wrongful and without justification, and was intended to enrich Regeneron at Humana's expense.

222. Regeneron's conduct and the resulting breaches directly and proximately caused Humana to suffer significant damages in the form of payments made on claims for Eylea that were not payable due to their underlying illegality, and would not otherwise have been made.

223. By virtue of the foregoing, Humana is entitled to recover compensatory and punitive damages in an amount to be determined at trial, as well as an injunction prohibiting Regeneron

from continuing to engage in the tortious conduct described herein and any other relief deemed just and proper.

COUNT III

AIDING AND ABETTING TORTIOUS CONDUCT

224. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

225. To the extent Regeneron did not carry out the scheme described herein itself, it provided substantial aid and encouragement to CDF to carry out the scheme. CDF also engaged in tortious conduct directed at Humana by interfering with Humana's contractual agreements with its members and fraudulently concealing Regeneron's scheme.

226. Humana's benefit plans, including its Medicare plans, require Humana members to pay the cost-sharing obligations when using prescription drugs, including Eylea.

227. CDF knew that Humana's members were parties to these benefit plans, and that the plans required members to pay cost-sharing obligations, as described above.

228. CDF intentionally interfered with those plan requirements by using the money it obtained from Regeneron to eliminate Humana's members' cost-sharing obligations by paying those obligations directly to the patients' providers who billed Humana.

229. CDF's conduct and interference caused Humana's members to breach their agreements with Humana when they failed to pay the cost-sharing obligations that Humana's benefit plans required.

230. CDF's interference was wrongful and without justification, and was intended to undermine the substance and structure of Humana's benefit plans and enrich Regeneron at Humana's expense.

231. Regeneron was aware of CDF's tortious conduct and encouraged it as described herein.

232. Regeneron also substantially assisted CDF in tortiously interfering with Humana's members' contracts by sending money to CDF that CDF used to pay providers to cover Humana's members' cost-sharing obligations.

233. Regeneron's wrongful assistance to CDF was a substantial factor in causing harm to Humana.

234. By virtue of the foregoing, Humana is entitled to recover compensatory and punitive damages in an amount to be determined at trial, as well as an injunction prohibiting Regeneron from continuing to engage in the tortious conduct described herein and any other relief deemed just and proper.

COUNT IV

VIOLATION OF CIVIL RICO, 18 U.S.C. § 1962(C)

235. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

236. Regeneron is a "person" within the meaning of 18 U.S.C. § 1961(3) that conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

237. Regeneron, CDF, and the Lash Group entered into an association-in-fact enterprise (the "Enterprise") within the meaning of 18 U.S.C. § 1961(4). The Enterprise was an ongoing organization that functioned as a continuing unit that was created and/or used as a tool to effectuate a pattern of racketeering activity, and had the common purpose of doing the same. Regeneron, CDF, and the Lash Group are each "persons" distinct from the Enterprise.

238. Regeneron established the Enterprise to inflate the price, and increase the sales, of Eylea. It enlisted CDF to launder illegal payments targeted to eliminate the cost-sharing obligations of Eylea patients. It further enlisted the Lash Group to advertise the availability of the resulting funds, to facilitate CDF funding for Eylea patients, and to monitor and facilitate reimbursements for Eylea by payors like Humana. The Enterprise worked to deceive payors like Humana into reimbursing claims for Eylea tainted by illegal kickbacks by means of fraud perpetrated over the wires or by mail.

239. Each participant in the Enterprise played a distinct and indispensable role, and the participants joined as a group to execute the scheme and further the Enterprise's goals. Regeneron marketed Eylea and made sham "donations" to CDF. CDF laundered Regeneron's sham "donations" and routed them to Eylea patients to eliminate their cost-sharing obligations. The Lash Group ensured through the EYLEA4U program that physicians and patients were aware of and able to utilize these funds, and facilitated payments from payors.

240. Each participant in the Enterprise profited from the Enterprise's illicit activities. Regeneron enjoyed windfall profits from sales of Eylea induced and facilitated by the Enterprise's deceptive scheme. CDF retained a portion of Regeneron's payment as "administrative fees." The Lash Group enjoyed payments from Regeneron in connection with its operation of EYLEA4U. The more Eylea sold at an artificially inflated price, the greater the profit to each member of the Enterprise. Accordingly, the actions of each participant directly benefitted not only that participant, but the other participants as well.

241. The Enterprise could not have succeeded, and its members could not have enjoyed the substantial financial benefits described above, absent their coordinated efforts. The members of the Enterprise functioned as a unit in pursuit of their common purpose.

242. The relationships between Regeneron, CDF, and the Lash Group extended beyond the unlawful predicate acts at issue in this case. For example, as discussed above, Regeneron's relationship with CDF predated the scheme at issue in this litigation. And the Lash Group operates other, lawful aspects of the EYLEA4U program, such as Regeneron's free drug program for uninsured patients. The formal contracts and informal agreements between the members of the Enterprise do not overlap perfectly with its racketeering activities. The illegal scheme at issue in this litigation was and is distinct from any legitimate business activities undertaken by Regeneron, CDF, and the Lash Group.

243. Each participant in the Enterprise knew that this scheme violated federal and state law as discussed herein.

244. The Enterprise engaged in and affected interstate commerce because it marketed Eylea throughout the United States, caused Eylea to be prescribed thousands of times, affected Eylea's pricing, subsidized Eylea's sales, and facilitated payments from Humana and other payors that fueled Eylea's commercial performance.

245. Regeneron asserted control over the Enterprise by funding it, procuring and providing the money CDF used to pay the cost-sharing obligations of patients enrolled in Humana's Medicare plans, and establishing the EYLEA4U program to further the Enterprise's scheme.

246. Regeneron conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to conduct unlawful activity).

247. The predicate acts of racketeering that Regeneron engaged in include: causing false claims and fraudulent claim certifications to be transmitted through the wires to Humana in order

to fraudulently induce Humana to pay for Eylea; using the wires to transmit and publish false statements that Regeneron did not influence or control CDF funding in order to fraudulently induce payors, including Humana, to pay claims for Eylea; and using the mails and wires to fraudulently conceal the Enterprise in order to induce payors, including Humana, to pay claims for Eylea.

248. Regeneron's Enterprise used the mails and wires to further its scheme by taking at least the following actions:

a. Coordinating the unlawful payments Regeneron made to CDF, including by the means of communication described herein;

b. Transferring unlawful payments from Regeneron to CDF, and from CDF to physicians positioned to prescribe Eylea;

c. Coordinating with the Lash Group to use the EYLEA4U program to facilitate payments from payors, including Humana, on claims for EYLEA that had been tainted by illegal kickbacks;

d. Disseminating false and misleading information to physicians, patients, and the general public (including Humana) regarding the availability of charitable funding and the nature of Regeneron's relationship with CDF;

e. Causing physicians to transmit false claims for Eylea that certified that they complied with federal and state law; and

f. Inducing Humana to use the wires to make payments on claims that were tainted by the Enterprise's illegal kickback scheme.

249. These actions reflect a continuous pattern of racketeering activity and the threat that the racketeering activity could continue.

250. As discussed above, the racketeering activity commenced in mid-2012 and continued for years thereafter to the present.

251. As also discussed above, Regeneron remains dependent on the windfall profits it reaps from Eylea through a high volume of sales at an artificially inflated price. These profits are only possible due to the scheme described above, which is Regeneron's regular manner of operating its business with respect to Eylea, and which Regeneron has a strong motive to perpetuate. The scheme is not inherently terminable, and can (and likely will) continue indefinitely so long as Regeneron continues to market Eylea.

252. Regeneron's racketeering activity has had the effect of causing payors, including Humana, to pay claims for Eylea that they otherwise would not have paid, and of keeping the price of Eylea at a level that was higher than the price it would have had but for Regeneron's unlawful conduct.

253. As described above, the Enterprise caused this result by: (1) funneling illegal funds to Eylea patients to render Eylea "cheaper" to those patients than competing drugs, and to subvert the cost-sharing obligations imposed by their insurance plans; (2) inducing doctors to prescribe, and patients to purchase, Eylea by advertising the availability of this funding, when in the absence of this funding, doctors and patients would have chosen Avastin; (3) inducing doctors and Eylea patients to apply for CDF funding and facilitating the application and approval process; and (4) facilitating claims for Eylea treatment from physicians to payors like Humana for Eylea treatment. The Enterprise exerted influence at every step in the process, targeting with

precision the "third-party payors" on which Regeneron's "[s]ales in the United States" are avowedly "dependent."[13] In doing so, the Enterprise directly damaged Humana.

254. Regeneron's racketeering activity directly and proximately caused Humana's damages, as described above.

255. By virtue of the foregoing, Regeneron is jointly and severally liable to Humana for three times the damages Humana sustained in an amount to be determine at trial, plus the cost of this suit, including reasonable attorneys' fees.

COUNT V

CONSPIRACY TO VIOLATE RICO, 18 U.S.C. § 1962(D)

256. Humana incorporates paragraphs 1 through 186 and 235 through 255 as if fully set forth herein and further alleges as follows.

257. 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

258. Regeneron violated 18 U.S.C. § 1962(d) by conspiring with CDF and the Lash Group to violate 18 U.S.C. § 1962(c). The object of the conspiracy was to conduct or participate in the conduct of the affairs of the Enterprise through a pattern of racketeering activity. And the purpose and effect of the conspiracy was to cause payors, including Humana, to pay claims for Eylea that they otherwise would not have paid, and to maintain inflated prices for Eylea.

259. Regeneron and its co-conspirators engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy.

260. The nature of the co-conspirators' acts, misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only conspired to violate

[13] Regeneron, 2019 Form 10-K Annual Report, at 24 (Feb. 7, 2020), https://tinyurl.com/y3zxyfkv.

18 U.S.C. § 1962(c), but also that they knew their ongoing acts were part of an overall pattern of racketeering activity.

261. Regeneron's overt and predicate acts in violation of 18 U.S.C. 1962(d) directly and proximately caused Humana to suffer injury in its business and property, as described above. Humana also suffered injury when it paid higher prices for Eylea that were the result of the unlawful and conspiratorial conduct.

262. By virtue of the foregoing, Regeneron is jointly and severally liable to Humana for three times the damages Humana sustained in an amount to be determine at trial, plus the cost of this suit, including reasonable attorneys' fees.

COUNT VI

UNJUST ENRICHMENT

263. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

264. Humana has conferred direct benefits on Regeneron in the form of significant payments based on claims submitted to Humana for Eylea treatments rendered to Humana's members, and Regeneron has knowledge of those benefits.

265. Regeneron has voluntarily accepted and retained the payments it has received and the other associated benefits conveyed to it by Humana as a result of Regeneron's scheme described herein.

266. Under the circumstances of this case, it would be inequitable for Regeneron to retain the benefits it has received at Humana's expense.

267. The money Regeneron has received from Humana belongs in equity and good conscience to Humana.

268. By virtue of the foregoing, Humana is entitled to recover the substantial amount of payments Regeneron has improperly retained.

COUNT VII

VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349 AND OTHER STATE DECEPTIVE TRADE PRACTICES LAWS

269. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

270. Humana is a person or consumer entitled to protection under New York's consumer protection law and other states' consumer protection laws.

271. Under New York General Business Law § 349(a), "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are . . . unlawful."

272. Regeneron's conduct was directed to and impacted Humana through the members Humana serves.

273. By engaging in the conduct described herein, Regeneron deceived Humana into making payments on claims for Eylea for its members based in New York that it otherwise would not have paid.

274. In addition to affecting Humana, Regeneron's conduct also affected other similarly-situated payors, as evidenced by the case filed by the United States against Regeneron.

275. Regeneron's scheme also deceived and affected the drug-consuming public at large. Skyrocketing drug prices present a significant harm to consumers, a burden on the United States healthcare system, and a substantial contributing factor to the overall rise in healthcare costs in the United States. Regeneron's scheme subverted the primary restraint on the price of Eylea, allowing Regeneron to inflate its price well beyond what the market would otherwise bear. The

ill effects of this scheme are ultimately borne not just by payors like Humana, but drug and healthcare consumers in the New York and elsewhere. In particular, any consumers who did not receive CDF funding, and whose doctors chose (for whatever reason) to prescribe Eylea over Avastin, were forced to pay far more for the drug than they would have absent Regeneron's fraud.

276. Regeneron's deceptive conduct directly and proximately caused Humana to suffer damages in the form of payments made on claims for Eylea that were not due and that would not otherwise have been made.

277. Moreover, in addition to violating New York's General Business law § 349, Regeneron's conduct described herein violated the laws of other states that prohibit deceptive trade practices, including the following laws:

a. **Arizona.** Regeneron engaged in deceptive practices in connection with its sale of Eylea, and suppressed material facts related thereto, as described above, in violation of Ariz. Rev. Stat. Ann. § 44-1521*, et seq.* Regeneron's actions deceived both Humana and its members, directly and proximately damaging Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

b. **California**. Regeneron engaged in unlawful, unfair, and fraudulent business practices in connection with its sale of Eylea, as described above, in violation of Cal. Bus. & Prof. Code § 17200*, et seq.* Regeneron's actions directly directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

c. **Colorado.** Regeneron engaged in deceptive trade practices and concealed material information concerning its sales of Eylea, as described above, in violation of Colo. Rev. Stat. § 6-1-101*, et seq.* Regeneron did so in the course of its business, its acts significantly impacted the public by inflating the price of Eylea through fraud, and these acts directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

d. **Florida.** Regeneron engaged in unfair, unconscionable, and deceptive acts and practices in connection with its sale of Eylea, as described above, in violation of Fla. Stat. § 501.201*, et seq.* These acts and practices directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

e. **Illinois.** Regeneron engaged in deceptive acts and practices in connection with its sales of Eylea, as described above, in violation of 815 Ill. Comp. Stat. 505/1*, et seq.* Regeneron intended to deceive Humana, and directly and proximately caused actual damages to Humana in the form of payments for Eylea that Humana would not otherwise have made and / or payments for Eylea at higher prices than it would otherwise have paid.

f. **Michigan.** Regeneron engaged in a deceptive course of conduct designed to mislead Humana as to the legality of claims for Eylea that were tainted by illegal kickbacks, as described above, in violation of Mich. Comp. Laws § 445.901*, et seq.* In doing so, Regeneron damaged Humana by inducing it to pay claims for Eylea that it

would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

g. **Minnesota.** Regeneron engaged in fraudulent and deceptive trade practices, as described above, in violation of Minn. Stat. § 325F.68*, et seq*. These practices directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

h. **Nebraska.** Regeneron engaged in unfair or deceptive acts or practices in connection with its sale of Eylea, as described above, in violation of Neb. Rev. Stat. § 59-1601*, et seq.* Regeneron's unfair and deceptive acts had a substantial impact on the public interest by artificially raising the price of Eylea, and directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

i. **Nevada.** Regeneron engaged in deceptive trade practices in connection with its sale of Eylea, as described above, in violation of Nev. Rev. Stat. § 41.600*, et seq.* Regeneron's actions directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

j. **New Hampshire.** Regeneron engaged in unfair and deceptive acts and practices in connection with its sale of Eylea, as described above, in violation of N.H. Rev. Stat. Ann. § 358-A:1*, et seq.* Regeneron's scheme was unethical and unscrupulous, caused substantial injury to consumers by inflating the price of Eylea, and directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not

have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

278. **North Carolina.** Regeneron engaged in unfair and deceptive acts or practices in connection with its sale of Eylea, as described above, in violation of N.C. Gen. Stat. § 75-1.1*, et seq.* Regeneron's scheme harmed consumers by inflating the price of Eylea, and directly and proximately damaged Humana by causing it to pay claims for Eylea that it would not have paid otherwise and / or to pay higher prices for Eylea than it would have paid otherwise.

279. Humana paid claims on Eylea treatment for members in each of the foregoing states as a result of Regeneron's fraudulent scheme.

280. Regeneron's conduct described herein offends public policy, is contrary to the public interest, and is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

281. Humana is therefore entitled to actual damages or damages for each deception that occurred, punitive damages, and attorney's fees.

COUNT VIII

VIOLATIONS OF STATE INSURANCE FRAUD LAWS

282. Humana incorporates paragraphs 1 through 186 as if fully set forth herein and further alleges as follows.

283. Defendants have committed insurance fraud in violation of the laws of Kentucky, Pennsylvania, and Tennessee; particularly the following laws:

284. Kentucky, Ky. Rev. Stat. § 304.47-010, *et seq.*;

285. Pennsylvania, 18 Pa. Cons. Stat. Ann. § 4117; and

286. Tennessee, Tenn. Code Ann. § 56-53-101, *et seq.*

287. Regeneron knowingly presented, or caused to be presented, to Humana statements in support of claims for benefits for Eylea that Regeneron knew contained false and/or misleading information. Defendants knew and intended that by engaging in their schemes to illegally subsidize copayments through phony charitable funds that misleading and/or false information would be submitted to Humana and other Medicare payors in connection with insurance claims. Regeneron knew that the presentation of false claims to Humana was essential to their scheme.

288. The compliance certifications and other information submitted to Humana were material to Humana's decision to pay for Eylea claims. Without them, Humana would not have paid these claims.

289. Humana injuries were directly and proximately caused by the false or misleading statements that Regeneron made to Humana, or cause to be submitted to Humana, as described above.

PRAYER FOR RELIEF

WHEREFORE, Humana respectfully requests that it be awarded the following relief:

a. Compensatory damages as requested herein;

b. Equitable relief as requested herein;

c. Injunctive relief as requested herein;

d. Treble damages under 18 U.S.C. § 1964(c);

e. Costs of court;

f. Reasonable attorney fees;

g. Prejudgment and post-judgment interest; and

h. An award of any other relief in law or equity that the Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: July 22, 2021

By: */s/ Ronald J. Schutz*

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